

MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
Educational Institution
BELARUSIAN STATE MEDICAL UNIVERSITY

APPROVED

by Rector of the Educational
Institution «Belarusian State
Medical University»



S.P.Rubnikovich

15.11.2023

Reg. # UD-091-037/2324/edu.

**Контрольный
экземпляр**

BIOMEDICAL STATISTICS

**Curriculum of the educational institution
in the academic discipline for the specialty**

7-07-0912-01 «Pharmacy»

Curriculum is based on the educational program «Biomedical Statistics», approved 15.11.2023, registration # УД-091-037/2324/уч.; on the educational plan in the specialty 7-07-0912-01 «Pharmacy», approved 17.05.2023, registration # 7-07-0912-01/2324/mf.

COMPILERS:

T.P.Pavlovich, Head of the Department of Public Health and Healthcare of the educational institution «Belarusian State Medical University», PhD, Associate Professor;

A.N.Charauko, Associate Professor of the Public Health and Health Care Department of the educational institution «Belarusian State Medical University», PhD;

I.I.Khalyamina, Senior Teacher of the Public Health and Health Care Department of the educational institution «Belarusian State Medical University»;

A.N.Stetsyk, Assistant of the Public Health and Health Care Department of the educational institution «Belarusian State Medical University»

RECOMMENDED FOR APPROVAL:

by the Department of Public Health and Healthcare of the educational institution «Belarusian State Medical University»
(protocol # 1 of 30.08.2023);

by the Scientific and Methodological Council of the educational institution «Belarusian State Medical University»
(protocol # 11 of 15.11.2023)

EXPLANATORY NOTE

«Biomedical Statistics» – is an academic discipline of the module «Information Technologies in Pharmacy» which contains a systematized scientific knowledge about statistical analysis methods applied in medicine and pharmacy.

The purpose of the academic discipline «Biomedical Statistics» is to form basic professional competences for solving problems of processing research results, describing biomedical research results using mathematical methods and statistical analysis methods (parametric and nonparametric ones).

The tasks of academic discipline «Biomedical Statistics» are to develop students' scientific knowledge about the main mathematical and statistical methods of processing the data obtained during the development and control of drugs, to equip them with skills necessary for:

the application of statistical analysis methods (parametric and nonparametric) in Pharmacy;

the description of the results of the use of statistical methods in biomedical research.

The knowledge, skills, and abilities acquired during the study of the academic discipline «Biomedical Statistics» are necessary for successful mastering of the following academic disciplines: «Medical and Biological Physics», «Analytical Chemistry», «Pharmaceutical Chemistry», «Pharmacy Organization and Economics», «Industrial Technology of Drugs», «Standardization of Drugs».

Student who has mastered the content of academic discipline education material should have the following basic professional competence:

UC. Master the basics of research, be able to search, analyze and synthesize information in medicine and biology.

BPC. Use basic mathematical and statistical methods for processing data obtained during the development and quality control of medicines.

As a result of studying the discipline «Biomedical Statistics» a student should

know:

basic concepts, features and techniques of the biomedical statistics methods application;

statistical methods of processing research results, probabilistic interpretation of results.

be able to:

perform statistical processing of research results;

determine factors affecting the completeness and accuracy of mathematical description of the processes under study, the credibility of assessments and findings;

apply the mathematical and statistical methods for solving professional tasks;

master:

basic terminology of biomedical statistics;

rules to present the statistical analysis data and findings.

Total number of hours for the discipline is 90 academic hours.

Classroom hours according to the types of studies: lectures – 12 hours

(including 4 hours of supervised independent work), practical classes – 28 hours, student independent work (self-study) - 50 hours.

Intermediate assessment is carried out according to the syllabus of the specialty in the form of a credit (2 semester).

The form of education is full-time.

**ALLOCATION OF ACADEMIC TIME
ACCORDING TO SEMESTERS OF STUDY**

Code, name of the specialty	semester	Number of academic hours						Form of intermediate assessment
		total	in-class	including			out-of-class self-studies	
				lectures (including supervised student independent work)	supervised student independent work	practical classes		
7-07-0912-01 «Pharmacy»	2	90	40	12	4	28	50	credit

THEMATIC PLAN

Topic name	Number of class hours	
	lectures	practical
1. Introduction to biomedical statistics. Basic concepts of evidence-based medicine	2	-
2. Fundamentals of probability theory	4	6
3. Mathematical statistics	6	20
4. Time series	-	2
Total hours	12	28

CONTENT OF THE EDUCATIONAL MATERIAL

1. Introduction to biomedical statistics. Basic concepts of evidence-based medicine

Biomedical statistics: contents and tasks. Special features of medical and statistical research organization. Ethical issues of biomedical research. Stages of medical and statistical research. Sampling, randomization. Concept of censored data. Randomization. Types of sampling techniques. Data analysis software.

Evidence-based medicine. Principles and methodological basis of evidence-based medicine. Goals and objectives of evidence-based medicine. Basic concepts in the fields of diagnosis (sensitivity, specificity, classification accuracy), treatment (randomization; single, double and triple blind study; placebo and nocebo effects) and literature analysis (medical research databases, systematic literature reviews and meta-analysis).

Types of clinical trials.

Types of data. Quantitative and qualitative variables. Measurement scales in statistics. Sample descriptive statistics and assessment of descriptive statistics in the general population.

2. Fundamentals of probability theory

Basic concepts of probability theory. Types of random events. Complete set of events. Sample space in probability. Classic and statistical definition of probability. Addition theorem on probability. Multiplication theorem on probability. Conditional probability. Law of total probability. Bayes's rule. Repeated independent trials. Bernoulli equation. The local and integral theorems of Laplace.

Discrete and continuous random variables. Numerical characteristics of discrete random variables. Binomial distribution. Poisson distribution. Distribution function and probability distribution density of continuous random variables. Normal distribution (Gaussian distribution). Limit theorems in probability theory. Lyapunov theorem.

Data visualization. Statistical tables: types and characteristics, requirements for presentation. Graph images: types, characteristics, requirements for presentation of graphs and diagrams. Graphs application in medicine and pharmacy. Stages of

constructing graphs using applied statistic programs.

Ways to present findings in scientific publications.

Usage of descriptive statistics in scientific publications. Application of specialized programs to obtain descriptive statistics.

3. Mathematical statistics

Mathematical statistics tasks.

Arithmetic mean, standard deviation, variance, coefficient of variation.

Sampling method. Statistical distribution of the sample. Discrete and interval distribution series. Distribution law for the discrete random variable. Selection and validation of comparative study of normality test: Shapiro-Wilk and Lilliefors criteria.

Graph images for the statistical data. Application of specialized statistical programs for the data graph presentation.

Concept definition of Statistical hypotheses. Null and alternative hypotheses. Basic principles of hypothesis testing. The level of statistical significance. Type I and Type II errors. Accepting the null hypothesis. Power analysis, statistical significance and effect size.

Probability. Confidence intervals for parameters of normal distribution.

One-tailed and two-tailed hypothesis tests explained.

Sample size determination.

Comparing two group means: the independent samples t-Test (t-criterion).

Comparison of the relative values.

Concepts of analysis of variance (ANOVA). One-way ANOVA.

Fisher's F-criterion.

Nonparametric Statistics.

Mann-Whitney U Test. Multiple comparisons problem. Non-parametric tests for three or more samples (Friedman and Kruskal-Wallis). Analysis of qualitative data. Chi-square statistics.

Correlation analysis. Functional and correlative dependencies. Form, power and direction of correlative connection. Pearson's correlation coefficient and assessment of its significance. Regression analysis, linear regression equation. Spearman's rank correlation.

4. Time series

Types of time series and their characteristics. Time series smoothing. Trends and seasonal variation of time series. Time series forecasting. Calculation of time series indicators.

ACADEMIC DISCIPLINE CURRICULAR CHART «BIOMEDICAL STATISTICS»

Section, topic #	Section (topic) name	number of hours			Self-studies	Form of control
		lectures (including supervised student independent work	supervised student independent work	practical		
1.	Introduction to biomedical statistics. Basic concepts of evidence-based medicine	2	0,5	-	2	Reports
2.	Fundamentals of probability theory	4	1	6	11	
	Event and probability	2	0,5	-	2	Reports
	Discrete and continuous random variables	2	0,5	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
	Generalizing indicators and data visualization in statistics and medicine	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
	Variational series	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
3.	Mathematical statistics	6	2,5	20	35	
	Sampling method	2	0,5	2	3	Reports, electronic tests, accounts of classroom (home) practical exercises with oral defense
	Diversity of variables in the totality	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
	Distribution of variables in the totality	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense

Statistical hypotheses	2	1	-	2	Reports
Parametric methods for testing statistical hypotheses (comparison of the averages of the two samples)	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Parametric methods for testing statistical hypotheses (comparison of the relative values)	-	-	2	3	Colloquiums. Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Analyses of variance	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Nonparametric methods for testing statistical hypotheses	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Correlation and regression analysis	2	1	-	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Correlation. Pearson correlation coefficient	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Regression analysis	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
Spearman's rank correlation coefficient	-	-	2	3	Interview, electronic tests, accounts of classroom (home) practical exercises with oral defense
4. Time series	-	-	2	2	Interview, accounts of classroom (home) practical exercises with oral defense.
Total hours	12	4	28	50	Credit

INFORMATION AND INSTRUCTIONAL UNIT

LITERATURE

Basic:

1. Глушанко, В. С. Общественное здоровье и здравоохранение = Public health and health service : пособие. - Витебск : ВГМУ, 2020. - 188 с.

2. Глушанко, В. С. Общественное здоровье и здравоохранение : руководство по практическим навыкам = Public health and health service : guide to practical skills : учеб.-метод. пособие. - Витебск : ВГМУ, 2020. - 130 с.

Additional:

3. Medical Statistics at a Glance - 4rd Edition : a textbook / A. Petri, C. Sabin. – Wiley, 2019. – 208p.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

Main forms of student independent work:

preparation for practical classes;

marking a research on topics and problems that have not been discussed in class;

fulfilling creative tasks;

preparation of reports, papers, presentations;

preparation for the colloquium and credit.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF A SUPERVISED INDEPENDENT STUDENT WORK IN THE ACADEMIC DISCIPLINE

Main forms of a supervised independent student work:

preparation of reports, essays, presentations;

presentation of reports;

studying topics and problems that have not been discussed at the lectures;

computer testing;

preparation of didactic materials.

Control of supervised independent student work is carried out in the form of:

discussion of reports, essays;

protection of study assignments;

assessment of an oral reply to a question, presentation, report or problem solving;

checking up abstracts, written reports, accounts, prescriptions;

individual interview;

final class, colloquium in the form of written work, testing.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

Oral form:

interviews;

reports.

Written form:

control questioning;

reports.

Oral-written form:

accounts of classroom (home) practical exercises with oral defense;

colloquium;

credit.

Technical form:

electronic tests.

LIST OF AVAILABLE TEACHING METHODS

Traditional method (practicals);

Active (interactive) methods:

Problem-Based Learning (PBL);

Team-Based Learning (TBL);

Research-Based Learning (RBL).

LIST OF PRACTICAL SKILLS

Name of practical skills	Practical skill control form
1. Visualization of statistical values	Problem-solving task
2. Calculation of average values. Characteristics of the diversity of variables in the sample	Problem-solving task
3. Drawing up an algorithm for applying the criterion of statistical significance	Problem-solving task
4. Assessing the reliability of the research result	Problem-solving task
5. Application of parametric and nonparametric criteria for testing statistical hypotheses	Problem-solving task
6. Performing analysis of variance, interpreting results	Problem-solving task
7. Determination of the correlation (Pearson correlation coefficient)	Problem-solving task
8. Conducting the regression analyses	Problem-solving task
9. Determination of the correlation (Spearman's correlation coefficient)	Problem-solving task
10. Calculate and analyze time series indicators	Problem-solving task
11. Use of specialized programs to solve typical practice-oriented tasks	Problem-solving task
12. Identify errors in reporting statistical analysis of medical data	Problem-solving task

LIST OF EQUIPMENT USED

Multimedia equipment (laptop, projector, screen).

Standard workstation with a personal computer.

Tables of critical values to determine the level of statistical significance of the calculated indicators.

LIST OF LECTURES

1. Introduction to biomedical statistics. Basic concepts of evidence-based medicine.
2. Event and probability.
3. Discrete and continuous random variables.
4. Sampling method.
5. Statistical hypotheses.
6. Correlation and regression analysis.

LIST OF PRACTICAL STUDIES

1. Discrete and continuous random variables.
2. Generalizing indicators and data visualization in statistics and medicine.
3. Variational series.
4. Sampling method.
5. Diversity of variables in the totality.
6. Distribution of variables in the totality.
7. Parametric methods for testing statistical hypotheses (comparison of the averages of the two samples).
8. Parametric methods for testing statistical hypotheses (comparison of the relative values).
9. Analyses of variance.
10. Nonparametric methods for testing statistical hypotheses.
11. Correlation. Pearson correlation coefficient.
12. Regression analysis.
13. Spearman's rank correlation coefficient.
14. Time series.

**PROTOCOL OF THE CURRICULUM APPROVAL «BIOMEDICAL STATISTICS»
OF THE MODULE «INFORMATION TECHNOLOGIES IN PHARMACY»
BY OTHER DEPARTMENTS**

Title of the discipline requiring approval	Department	Amendments to the curriculum in the academic discipline	Decision of the department, which designed the curriculum (date, protocol #)
Medical and biological physics	Department of medical and biological physics	No amendments	Protocol # 1 of 30.08.2023
Analytical chemistry	Department of Pharmaceutical Chemistry	No amendments	Protocol # 1 of 30.08.2023
Pharmaceutical chemistry	Department of Pharmaceutical Chemistry	No amendments	Protocol # 1 of 30.08.2023
Pharmacy organization and economics	Department of Organization and Economics of Pharmacy	No amendments	Protocol # 1 of 30.08.2023
Industrial technology of drugs	Department of Pharmaceutical Technology	No amendments	Protocol # 1 of 30.08.2023
Standardization of drugs	Department of Pharmaceutical Chemistry	No amendments	Protocol # 1 of 30.08.2023

COMPILERS/AUTHORS:

Head of the Department of Public Health and Healthcare of the educational institution «Belarusian State Medical University», PhD, Associate Professor

T.P. Pavlovich

Associate Professor of the Department of Public Health and Healthcare of the educational institution «Belarusian State Medical University», PhD

A.N. Charauko

Senior teacher of the Department of Public Health and Healthcare of the educational institution «Belarusian State Medical University»

I.I. Khalyamina

Curriculum content, composition and the accompanying documents comply with the established requirements.

Dean of the Medical Faculty for International Students of the educational institution «Belarusian State Medical University»

13 11 2023

Oleg S. Ishutin

Methodologist of the educational institution «Belarusian State Medical University»

13 11 2023

S.V. Zaturanova