



FACULTY OF MEDICINE

STUDY PROGRAM 0912.1 MEDICINE

Nicolae Testemitanu Chair of Social Medicine and Health Management

APPROVED

at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum faculty Medicine

Minutes No. 6 of 22.02.18

Chairman, PhD, associate professor

Suman Serghei

(signature)

APPROVED

at the Council meeting of the Faculty Medicine no. II

Minutes No. 6 of 20.09.17

Dean of Faculty, PhD, associate professor

Bețiu Mircea

(signature)

APPROVED

approved at the meeting of the chair Nicolae Testemitanu Social Medicine and Health Management

Minutes No. 6 of 15.01.18

Head of chair, PhD, professor,

Tintiuc Dumitru

(signature)**SYLLABUS**DISCIPLINE **BIostatistics. Methodology of Scientific Research****Integrated studies**Type of course: **Compulsory**

Chisinau, 2018



CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page. 2/8

I. INTRODUCTION

- **General presentation of the discipline: place and role of the discipline in the formation of the specific competences of the professional / specialty training program**

The course "Biostatistics. Methodology of Scientific Research" covers the theoretical and practical aspects related to the realization of a scientific research and the statistical data analysis. The course has the content similar to other European universities with up-to-date information, and it equips students with the necessary baggage of knowledge in order to carry out a scientific research in the field of biomedical science. The course presents a predominantly applicative approach to the statistical methods needed to solve practical problems in the biomedical field.

- **Mission of the curriculum (aim) in professional training:**

Assimilation of the theoretical and practical knowledge necessary for carrying out a scientific research in the medical sciences, including the licentiate thesis.

- Language (s) of the course: English, French.
- Beneficiaries: students of the II year, faculty Medicine II.

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline	U.03.O.021		
Name of the discipline	Biostatistics. Methodology of Scientific Research		
Person(s) in charge of the discipline	Raevschi E., Penina O., Obreja G.		
Year	II	Semester/Semesters	III
Total number of hours, including:			120
Lectures	17	Practical/laboratory hours	
Seminars	51	Self-training	52
Clinical internship			
Form of assessment	E	Number of credits	4

III. TRAINING AIMS WITHIN THE DISCIPLINE

At the end of the discipline study the student will be able to:

✓ *at the level of knowledge and understanding:*

- To know and to apply appropriately the notions specific to the discipline, as well as the theoretical and practical contents of the discipline;
- To know the rules and steps of research process in biomedical sciences;
- To know the types of data and the principles of their classification;
- To know and to understand the scales of measurement of the data;
- To know how to collect the data;
- To understand the methods of data summarizing depending on the type of data;
- To know and to understand the principles of performing the descriptive and inferential statistical data analysis;
- To know the main types of statistical tests;
- To know the principal statistical tests and the algorithm of selection of a specific test depending on the type of data and the type of research;
- To be familiar with the rules of use of biostatistics in the analysis of the population's health;
- To characterize the main types of epidemiological studies, their advantages and disadvantages;
- To know the ethical rules in research;
- To know the rules and techniques of avoiding plagiarism;
- To be familiar with the requirements for the licentiate thesis.

✓ *at the application level:*

- To apply the methods of descriptive and inferential statistics to quantitative and qualitative data;



CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page. 3/8

- To present qualitative and quantitative data graphically;
- To apply the direct method of standardization of rates and to interpret the results;
- To elaborate correctly research hypothesis;
- To apply correctly a statistical test depending on the type of data;
- To select and to apply correctly statistical tests in the hypothesis testing process;
- To analyze and to interpret the results of epidemiological studies;
- To provide a critical overview of a medical scientific article;
- To create Power Point Presentation for a specific topic and to defend it;
- To present the results of biomedical research publicly.

✓ *at the integration level:*

- To assess the place and role of biostatistics and research methodology in the professional medical career;
- To integrate the knowledge in biostatistics and research methodology with clinical disciplines;
- To apply the knowledge in biostatistics and research methodology to practical and research activities;
- To be competent to use information critically from scientific publications in own researches using the new information and communication technologies.

IV. PROVISIONAL TERMS AND CONDITIONS

1. Language requirements;
2. Basics of the school mathematics ;
3. Basic computer skills (MS Office Word, EXCEL, PowerPoint);
4. Ability to work in a team.

V. THEMES AND ESTIMATE ALLOCATION OF HOURS

Lectures, practical hours/ laboratory hours/seminars and self-training

Nr. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self- training
1.	Biostatistics and Research Methodology –general concepts and definitions. Design and steps of research process.	2	3	2
2.	Data collection. Sampling. Statistical questionnaire.	-	2	4
3.	Descriptive statistics. Absolute and relative measures. Statistical indicators. Data standardization. Methods of standardization. Direct method of standardization.	1	6	4
4.	Descriptive statistics. Measures of Central Tendency. Properties. Advantages and disadvantages. Interpretation of outliers. Analysis of variability. Types of variability measures. Shape of distribution and its asymmetry.	1	6	4
5.	Descriptive statistics. Correlation and regression.	1	3	2
6.	Analysis of time variation of phenomena. Chronological series.	-	3	2
7.	Inferential statistics. Hypothesis testing. Parametric and non-parametric tests.	2	6	4
8.	Graphical presentation of data.	1	3	2
9.	Types of epidemiological study designs. Descriptive study designs. Classification, methodological principles. Analysis and interpretation of results. Advantages and disadvantages.	1	3	2
10.	Analytic and observational study designs. Classification, methodological principles. Analysis and interpretation of results. Advantages and disadvantages. Application of information technologies in research.	2	6	4
11.	Randomized clinical trials. Classification, methodological principles. Analysis and interpretation of results. Advantages and disadvantages. Evaluation of	2	3	2



CD 8.5.1 DISCIPLINE CURRICULUM

Edition:	06
Date:	20.09.2017
Page. 4/8	

Nr. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
	diagnostic tests. Meta-analysis as a critical evaluation of validity and relevance of scientific results.			
12.	Communication skills. Analysing, interpreting and presenting the results of scientific research. Public presentation of a research project.	2	7	20
13.	Protection of intellectual property. Ethics of scientific research.	2	-	
Total		17	51	52

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Descriptive statistics	
<ul style="list-style-type: none"> • <i>To define</i> the basic terminology used in descriptive statistics; methods of summarizing and graphical presentation of the data depending on their type; • <i>To know</i> how to analyse qualitative and quantitative data with descriptive summary statistics and graphs; the conditions under which different types of correlation coefficients are used and their interpretation; • <i>To demonstrate</i> capacities to select adequately descriptive statistics and graphs for data summarizing and to interpret the obtained results; • <i>To apply</i> the methods of descriptive statistics for the quantitative (grouped and ungrouped) and qualitative data processing; the calculation techniques of the main correlation coefficients; the direct method of standardization of rates. • <i>To integrate</i> the knowledge obtained in the given field for processing qualitative and quantitative data obtained in a scientific research. 	<ol style="list-style-type: none"> 1. Basic terminology in biostatistics. Descriptive and inferential statistics. Population and sample. Observational unit. Variable. Parameters and statistics. Scales of measurement. Types of sampling. Statistical questionnaire: classification, structure, design. Summarizing and graphical presentation of qualitative and quantitative data. Frequency distribution. 2. Measures of central tendency: mean, median, mode. Calculation of measures of central tendency for the ungrouped and grouped data. Relative location of measures of central tendency in a unimodal distribution (normal and skewed). Histogram and frequency polygon. Normal (Gauss) frequency distribution. Analysis of the shape of the frequency distribution and the degree of its asymmetry. Quartiles (Q1, Q2, Q3), interquartile range (IQR), deciles and percentiles. 3. Measures of variability: range, variance, standard deviation, coefficient of variation. Standardization and z-scores. Definition, calculation and interpretation of the results. Empirical rule. Five summary statistics and “boxplot”. 4. Summarizing qualitative data with numbers. Absolute and relative measures. Statistical indicators: ratio, proportion and rate. Types of rates. Direct method of standardization of rates. Analysis of time variation of phenomena. 5. Correlation and regression. Correlation: definition, size and direction. Parametric and non-parametric correlation coefficients. Conditions of application and interpretation of results. Correlation coefficient r (Bravais-Pearson). Rank correlation coefficient (Spearman). Chi-square contingency coefficient (χ^2). Yule's coefficient of association. Graphical visualization of correlation with scatterplots. Coefficient of determination (r^2). Regression: definition, types of regression. Simple and multiple linear regression. Logistic regression (definition).
Theme (chapter) 2. Inferential statistics	



CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page: 5/8

Objectives	Content units
<ul style="list-style-type: none">• <i>To define</i> the basic theoretical concepts related to the inferential statistics;• <i>To know</i> the vocabulary used in the field of hypothesis testing and the main steps of application of a statistical test;• <i>To demonstrate</i> the correct selection, application and interpretation of a statistical test;• <i>To apply</i> the methods of inferential statistics studied within the course;• <i>To integrate</i> the obtained knowledge in the field of inferential statistics with clinical disciplines to carry out a scientific research.	<ol style="list-style-type: none">1. Inferential statistics: the basic concepts. Classical definition of probability. The Law of Large Numbers. The Central Limit Theory. The random sampling distribution of means.2. Estimation of population parameters. Standard error. Confidence intervals. Definition and calculation. Interpretation.3. Hypothesis testing. Null and alternative hypothesis. Types of error in hypothesis testing. Type I and type II errors. The significance (alpha) level and <i>p</i>-value. Confidence level and statistical power of the test. Statistical and clinical significance.4. Basic steps of hypothesis testing. Types of statistical tests. Parametric and non-parametric statistical tests. Statistical tests for dependent and non-dependent samples. Selection of the statistical test depending on the number of samples and data distribution. Conditions of application. Interpretation of results.

Theme (chapter) 3. Research Methodology

<ul style="list-style-type: none">• <i>To define</i> the basic terminology used in research methodology; the characteristics of the main steps of research process;• <i>To know</i> the methodological principles, advantages and disadvantages of the epidemiological study designs;• <i>To demonstrate</i> the capacities required to conduct the descriptive and analytic epidemiological studies;• <i>To apply</i> methods for calculating the main indicators used in analytic epidemiological studies and to interpret correctly their results;• <i>To integrate</i> the knowledge gained in the field of Research Methodology with clinical and scientific activities.	<ol style="list-style-type: none">1. Basic concepts in the field of research methodology. Research: definition, classification, methodological principles and characteristics. Study design. Research hypothesis. Steps of research process. Sampling and its types. (probability and non-probability). Sample size determination. Representativeness, accuracy and precision of a sample. Types of errors in research (systematic bias and random error). Validity of a study (internal, external and generalizability of study results).2. Key concepts of epidemiology. Vital statistics. Incidence and prevalence. Classification of the epidemiologic study designs. Descriptive, analytic studies and meta-analysis. Hierarchy of epidemiologic study designs. Contingency 2x2 table in epidemiologic studies.3. Descriptive study designs. Case-report and case-series study designs. Cross-sectional study design. Ecological studies. Methodological principles, advantages and disadvantages. Interpretation of results.4. Observational analytic study designs. Case-control and cohort study designs. Methodological principles, advantages and disadvantages. Contingency 2x2 table used in case-control and cohort studies. Calculation and interpretation of the measures of association used in case-control study (Odds Ratio) and cohort studies (Relative Risk, Attributable Risk, Attributable Risk Fraction). Framingham heart study.5. Analytic and experimental study designs: clinical trials. Randomized clinical trials with parallel, sequential (crossover) and external controls. Methodological principles, advantages and disadvantages. Contingency 2x2 table used in Clinical Trials. Analysis of clinical trials (Relative Risk, Relative Risk Reduction, Absolute Risk reduction, Number Needed to Treat). Interpretation of the results6. Evaluation of diagnostic tests. Contingency 2x2 table used in evaluation of diagnostic test. Measures of diagnostic accuracy: sensitivity (Se), Specificity (Sp), Positive Predictive Value (PPV) and Negative Predictive Value (NPV). ROC curve. Interpretation of results.
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CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page: 6/8

VII. PROFESSIONAL (SPECIFIC (SC)) AND TRANSVERSAL (TC) COMPETENCES AND STUDY OUTCOMES

✓ Professional (specific) (SC) competences

- CP2.**
- To know and to apply properly the fundamental concepts in the field of biostatistics and research methodology required to carry out scientific research and statistical processing of data;
 - To elaborate correctly a statistical protocol specific to a particular epidemiological study design (descriptive, analytical, clinical trials);
 - To perform descriptive statistical analysis of the experimental data, including their graphic representation;
 - To formulate correctly the statistical hypothesis, to select and to use the most appropriate statistical tests depending on the nature of the data and the type of study;
 - To identify the main sources of systematic biases and random errors in an epidemiological study.
- CP4.**
- To apply statistical analysis techniques for practical biomedical problems
- CP5.**
- To use properly the methods of population health data analysis
- CP6.**
- Ability to elaborate a scientific paper in the biomedical field (e.g., licentiate thesis, scientific article, conference report, etc.), to analyse and to interpret critically scientific papers.

✓ Transversal competences (TC)

- CT1.**
- To understand the importance of statistical analysis of data in the modern context of "evidence-based medicine";
 - To use the knowledge of statistical analysis in the context of other disciplines, as well as in solving practical problems. Ethics in scientific research.
- CT2.**
- Student's development and empowerment;
 - Student's openness to lifelong learning.
- CT3.**
- To demonstrate the involvement in scientific activities, such as the elaboration of scientific articles and researches in the biomedical field;
 - The oral and written communication of the results of a scientific research, including the licentiate thesis.

✓ Study outcomes

The student at the end of the course will be capable:

- To explain the basic concepts with regard to the organization of a scientific research and publication of the results;
- To develop a research project in the biomedical field;
- To process statistically the experimental data depending on its nature and to interpret the results of the statistical inference;
- To determine the statistical methods for data analysis taking into account the study design, the scale of measurement, the number of variables involved (independent and dependent);
- To characterize the basic features of the epidemiological study designs (descriptive, analytical and meta-analysis), their advantages and limitations;
- To perform an epidemiological study (descriptive or analytical) and interpret its results correctly;
- To develop a scientific paper, including the license thesis, and to capitalize on its results;
- To assess the role and importance of biostatistics and the research methodology in the modern context of "evidence based medicine";
- To have openness to lifelong learning.

Note. Study outcomes (are deduced from the professional competencies and formative valences of the informational content of the discipline).



CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page. 7/8

VIII. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
1.	Working with information sources	To read the material carefully for the corresponding theme from the textbook. To answer to the questions given at the end of each theme. Formulation of conclusions.	The ability to extract the essentials, the ability to interpret and to present the didactic material.	During the semester
2.	Performing a PowerPoint research project and its public defense.	Selection of the research theme, elaboration of the research plan and program, carrying out the research with respect to the planned stages according to the plan for the realization of the Research Project for students in the discipline "Biostatistics. Methodology of Scientific Research".	The volume of work, the degree of penetration into the researched problem, the correctness of applying the descriptive and inferential statistics methods, the quality of the conclusions, the quality of the public presentation.	During the semester
3.	Solving the practical problems	Practical problems are solved after analyzing the information on the topic in the textbook. Some practical problems can be solved on the computer with MS Office EXCEL in the computer room of the Department.	Solving the problems of the situation, the quality of conclusions.	During the semester

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

- **Teaching and learning methods used**

For more effective learning in the course "Biostatistics. Methodology of Scientific Research", both traditional methods (exposure, conversation, exercise) and those considered today to be more effective for university education (active based learning based learning, case study, project method, modeling) are used. Practical methods use frontal methods, individual activity methods, group activity methods. Practical training within the course uses computer-assisted training / self-training (MS Office EXCEL, PowerPoint).

- **Applied teaching strategies / technologies (specific to the discipline)**

Communication Technologies such as PowerPoint presentations are used during the theoretical lectures and practical seminars.

- **Methods of assessment (including the method of final mark calculation)**

- ✓ **Current:**

The current assessment during the semester includes 3 midterm tests (the theoretical part) and a student's Power Point presentation of the research project (the practical part). The latter represents the assessment of the practical skills of a student.

Theoretical part:

- Midterm test nr.1 - Descriptive statistics
- Midterm test nr.2 - Inferential statistics
- Midterm test nr.3 - Methodology of scientific research

Practical part:

- Project presentation + attendance of the theoretical lectures.

The mark for the practical part of the current assessment is complex and consists of two parts: the mark for the project presentation (coefficient is 0.9) and the mark for the attendance of the theoretical lectures (coefficient is 0.1). The semester mark is calculated as the average of three midterm tests and the project presentation mark.

Final: examination.



CD 8.5.1 DISCIPLINE CURRICULUM

Edition: 06

Date: 20.09.2017

Page. 8/8

The examination for the discipline “Biostatistics. Research Methodology” represents the grid-test. It includes **50** random questions from each of the studied themes with 40% single-choice questions and 60% multiple-choice questions. The student has at his/her disposal 50 minutes to answer to the grid-test. Those students who have the semester mark less than 5.0 and / or did not recover their absence(s) for the practical seminars are not admitted to the final examination.

The **final mark** is calculated as the average of the semester mark and the mark for the test-grid obtained at the exam.

Method of mark rounding at different assessment stages

Intermediate marks scale (annual average, marks from the examination stages)	National Assessment System	ECTS Equivalent
1,00-3,00	2	F
3,01-4,99	4	FX
5,00	5	E
5,01-5,50	5,5	
5,51-6,0	6	
6,01-6,50	6,5	D
6,51-7,00	7	
7,01-7,50	7,5	C
7,51-8,00	8	
8,01-8,50	8,5	B
8,51-8,00	9	
9,01-9,50	9,5	A
9,51-10,0	10	

The average annual mark and the marks of all stages of final examination (computer assisted, test, oral) - are expressed in numbers according to the mark scale (according to the table), and the final mark obtained is expressed in number with two decimals, which is transferred to student's record-book.

Absence on examination without good reason is recorded as "absent" and is equivalent to 0 (zero). The student has the right to have two re-examinations.

X. RECOMMENDED LITERATURE:

A. Compulsory:

1. **RAEVSCI E., TINTIUC D.**, 2012. *Biostatistics & Research Methodology*. Methodological recommendation for medical students. Chisinau: Medicina, 94 p.
2. **RAEVSCI E., PENINA O.**, 2016. *Reporting of Findings of Medical Research: Term Project Presentation Guide*. Methodological recommendations for the course in Biostatistics and Research Methodology for medical students. Chisinau: Medicina, 27 p. (accesibil în format electronic pentru studenți prin SIMU).

B. Additional

1. **GLASER ANTHONY N.**, 2013, *High-Yield Biostatistics, Epidemiology, and Public Health*, Fourth edition, Philadelphia, LWW, 168 p.
2. **TINTIUC D., BADAN V., RAEVSCI E.**, et al., 2011. *Biostatistica și Metodologia Cercetării Științifice* (suport de curs). Chișinău: Medicina, 344 p. (în română).
3. **URDAN T. C.**, 2010, *Statistics in Plain English, Third Edition*, 3 edition, New York, Routledge, 224 p.