FACULTY OF STOMATOLOGY

STUDY PROGRAM 0911.1 STOMATOLOGY

CHAIR OF MANAGEMENT AND PSYCHOLOGY

APPROVED

at the meeting of the Committeee for Quality Assurance and Evaluation of the Curriculum Faculty of Stomatology

Minutes No.___ of _____

Committee president, PhD DMS, associate professor.

Stepco Elena _____

APPROVED

at the Council meeting of the Faculty of Stomatology

Minutes No.___ of _____

Dean of Faculty of Stomatology, PhD DHMS, professor.

Ciobanu Sergiu _____

APPROVED

at the meeting of the chair Management and Psychology

Minutes No.11 of 14.02.2018

Head of chair, PhD in medicine, univ. professor

Larisa Spinei_____

CURRICULUM

DISCIPLINE **BIOSTATISTICS AND REASERCH METHODOLOGY**

Integrated studies

Type of course: **Compulsory**

Chisinau, 2018

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**

Biostatistics represents statistical processes and methods applied to the collection, analysis, and interpretation of biological data and especially data relating to human biology, health, and medicine

Biostatistics is the science that studies the structure and dynamics of the population health in relation with social, economic, medical, biological and cultural determinants, having as a purpose to determine the trends of this state and to take measures in order to improve population health.

Medicine is an ever-changing science. As new research and clinical experience broaden our knowledge, changes in treatment and drug therapy are required. At present, due to the rapid scientific progress, there is a huge amount of information, which has to be used successfully and applied in practical activities. This implies the presence of knowledge and skills, concerning analysis and synthesis of information, in order to find regularities and formulate accurate conclusions. Therefore, the study of biostatistics at the university level will help future doctors to solve problems related to the analysis of information about health status of population and apply confidently the results of medical studies to patient care.

The **necessity** and usefulness of studying biostatistics emerges from the following.

Biostatistics knowledge will help students to evaluate critically the literature, to apply study results to patient care, to interpret vital statistics, to understand epidemiologic problems, to interpret information about drugs and equipment, to use diagnostic procedures, to keep abreast of current trends and to be critical about data, to evaluate study protocols, articles etc.

Knowing this area offers physicians the opportunity to evaluate objectively their own results from the activity, the results of the medical institutions, the scientific literature in the field, but also to be involved in various scientific research activities.

The importance of biostatistics and research methodology has increased greatly in recent years because the students are involved in various scientific researches within the license thesis. In order to successfully carry out various researches, students should know basic biostatistics and research methodology, be familiar with various types of epidemiological studies, use various methods of sampling selection, and calculate different types of indicators, assesses the veracity the obtained results, present them with tables and graphs and formulate the correct conclusions.

Mission of the curriculum (aim) in professional training

To provide knowledge about main concepts of biostatistics and research methodology and develop skills and competences concerning collection, analysis, and interpretation of biological and medical data in order to apply the results to patient care.

- **Language (s) of the course**: Romanian, English.
- **Beneficiaries:** students of the III year, Faculty of Stomatology.

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		S.06.O.072	
Name of the discipline		**Biostatistics and research methodology**	
Person(s) in charge of the discipline		**Spinei Larisa**, PhD, professor **Globa Nina,** MPHM	
Year	**III**	Semester	**VI**
Total number of hours, including:	**60**		
Lectures	**17**	Practical/laboratory hours	**17**
Seminars	**17**	Self-training	**9**
Clinical internship			
Form of assessment	**CD**	Number of credits	**2**

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:*
  - Define basic concepts of biostatistics.
  - List and describe research methods.
  - Describe summary statistics types.
  - Classify the characteristics of the unit of observation.
  - Explain the application of probability theory and law of major figures in Biostatistics.
  - Explain how to calculate the probability by Laplace's formula.
  - Explain the essence of representative error "m" and the error permissible limit "Δ".
  - Appoint sampling advantages.
  - List the types of sampling.
  - Describe the advantages and disadvantages of different types of selection.
  - List and describe the main types of relative indicators: rate, ratio, proportion.
  - Describing the stages of establishment of the series variables.
  - Characterize the average, mode and median.
  - Describe the stages of standardization by direct method.
  - List and describe the types of time series.
  - Describe the stages of a study.
  - Describe ways of presenting statistical data.
  - Define the basics concepts of epidemiology.
  - List the scope of epidemiology.
  - Describe the aim, objectives and methods of descriptive epidemiological investigation.
  - List the main areas of application and basic features of experimental and operational investigations.
  - Describe the main features of cohort, case-control and randomized clinical trials.
  - Describe the advantages and disadvantages of different types of studies: descriptive, case - control, cohort and randomized.
  - Appoint and characterize demographic indicators.

- Appoint and characterize population morbidity indices: incidence and prevalence.
- Name and describe the types of literature analysis.
- Describe the parts of a scientific article.

- *at the application level student will be able to:*
  - Apply different methods of collecting and processing information.
  - Use formulas to determine the size of a representative sample of different types of studies.
  - Calculate relative indicators: rates, ratios and proportions.
  - Calculate the indicators of central tendency: simple and weighted mean, median, mode, geometric mean etc.
  - Analysis of simple indicators of variation: the range, interquartile range, deviation of each value from its mean.
  - Analysis of synthetic indicators of variation: the variance and the standard deviation.
  - Calculation and interpretation of the coefficient of variation.
  - Calculation and interpretation of the standard error and confidence interval.
  - Use testing methods for variability.
  - Apply nonparametric tests in comparison of absolute, relative and central tendency indicators.
  - Calculate the time series indices: index of dynamic and rhythm of dynamics.
  - Apply the direct method of standardization in comparison of statistical index.
  - Calculate and interpret the coefficient of correlation.
  - Apply coefficient of regression for determining the direction and intensity of dependence between phenomena.
  - Make tables and diagrams under the standard requirements.
  - Design a descriptive study.
  - Design a cohort study.
  - Measure the associations between expose and result in a cohort study.
  - Design a case – control study.
  - Measure the associations between expose and result in a case-control study.
  - Design a randomize trial and calculate indicators for this type of study.
  - Evaluate critically various scientific publications.
  - Make a correct list of the studied literature.
  - Calculate and interpret certain demographic and morbidity indicators.

- *at the integration level:*
  - Argue the necessity of biostatistics studying by students - physicians.
  - Organize a scientific research using theoretical knowledge and practical skills obtained during the study course.
  - • Prepare an article for publication.
  - • Apply gained knowledge in the analysis of demographic and morbidity processes of population.

IV. PROVISIONAL TERMS AND CONDITIONS

For successful acquisition and successful completion of the course, students must have a thorough knowledge of mathematics, biology, informatics and basic knowledge in medicine, public health and

epidemiology.

V. THEMES AND ESTIMATE ALLOCATION OF HOURS

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

Nr.	Topics	Lectures	Seminars	Practical	Self training
1.	Biostatistics as a Science and Subject of Study. Theoretical and Methodological foundations of Biostatistics.	1	1	1	
2.	Probability Theory and Hypotheses Testing Introduction. The Law of Large Numbers. Samples and Methods of Sampling.	1	1	1	
3.	Statistical Indicators: Definition, Functions, Classification. Primary and Secondary Indicators. Relative Values.	1	1	1	1
4.	The Statistical Series of Variation. Numerical Data Summarizing. Measures of Central Tendency.	1	1	1	1
5.	Analysis of Variability.	2	1	1	1
6.	Hypothesis Testing Parametric and Non-Parametric Methods.	1	1	1	1
7.	Time Series and their Analysis.	1	1	1	1
8.	Adjusted Rate: Direct Method of Standardization.	1	1	1	
9.	Correlation and Regression	1	1	1	1
10.	Basic concepts of epidemiology and Study designs.	1	1	1	
11.	The Research Methodology Introduction. Preparing the Research Design.	1	1	1	1
12.	The Descriptive Studies	1	1	1	
13.	The Cohort Studies	1	1	1	
14.	The Case-Control Studies		1	1	
15.	The Clinical Trials Studies	1	1	1	
16.	Types of literature analysis. Critical evaluation of Scientific Researches	1	1	1	1
17.	Reporting the Findings of the Research in Various Forms: Written, Graphic and Oral.		1	1	1
	Total	**17**	**17**	**17**	**9**

VI.   REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Biostatistics as a Science and Subject of Study. Theoretical and Methodological foundations of Biostatistics.	
• Define the basic concepts of Biostatistics. • Appoint the purpose and objectives of biostatistics. • List and describe research methods. • Describe types of statistical totals. • Classify the characteristics of the observation unit. • Describe the development stages of the statistics**.**	1. The biostatistics: definition, theoretical foundations, objectives and compartments. 2. The object of study and most important features of biostatistics. Reasons for learning biostatistics 3. Methods of investigation in biostatistics. Method of information collecting. 4. The types of statistical totalities, examples. Requirements for partial statistical totality. 5. The unit of observation: definition, basic characteristics, examples. 6. Classifications of statistical signs, characteristics, use examples. 7. The Scales of measurement: nominal, ordinal and numerical, examples of date.
Theme (chapter) 2. Probability Theory and Hypotheses Testing Introduction. **The Law of Large Numbers. Samples and Methods of Sampling.**	
• Explain how to apply the probability theory and the law of large numbers in biostatistics. • Explain how to calculate probability according to Laplace's formula. • Explain the essence of the representative error "m" and the admissible limit error "Δ". • Name the benefits of sampling. • List the types of sampling. • Describe the advantages and disadvantages of different types of selection. •Use formulas to determine representative sample size for different types of studies.	1. Defining and interpretation of probability theory. 2. The law of large numbers and its application. 3. Central limits theorem. 4. Populations and samples. Reasons for sampling. 5. The types of probability and non-probability sampling.
Theme (chapter) 3. Statistical Indicators: Definition, Functions, Classification. Primary and Secondary Indicators. Relative Values.	
• • List and describe the main types of statistical indicators • To characterize the relative indicators: rate, ratio, proportion. • Make comparative analysis and identify the specificity of different relative indicators • Calculate, based on the case, various rates, ratios,	1. The statistical data. Classification and their feature. 2. The statistical indicators: types and functions. 3. The relative value: types, general characteristics and methodology of calculation. 4. The rates: definition, components, types,

proportions. • List different areas of application of relative indicators.	application, examples. 5. Proportions. Definition. Components. Application. Examples. 6. Ratios. Definition. Components. Application. Examples.

Theme (chapter) 4. The Statistical Series of Variation. Numerical Data Summarizing. Measures of Central Tendency.

• Describe the series of variation and steps of their forming. • To characterize the central trend indicators • Specify the arithmetic mean peculiarities. • Calculate the central trend indicators: average, median and mod, and make conclusions based on the results.	1. The statistical series of variation. Specific feature of variation series. 2. The general characteristic of central tendency measures. 3. The mean: types and its properties. 4. The central tendency indicators of position: mode and median.

Theme (chapter) 5. **Analysis of Variability.**

• Explain the usefulness of variance indicators. • To characterize and calculate simple indicators of variation. • Calculate and draw conclusions based on the synthetic variables. • Describe and illustrate different types of data distribution. • Conclude about the homogeneity and variability of data based on the coefficient of variation.	1. Variability - general concepts. The classification variability indicators. 2. The analysis of simple indicators of variation: the range (R), interquartile range (IQR), maximum positive and negative deviations, deviation of each value from its mean (d) 3. The analysis of synthetic indicators of variation: the variance (σ^2) and the standard deviations (σ) 4. Calculation and interpretation of the coefficient of variation.

Theme (chapter) 6. **Hypothesis Testing Parametric and Non-Parametric Methods**.

• To name and describe the parametric and non-parametric tests of hypothesis testing. • Apply the methods of the relative value testing: calculate the standard error, the confidence interval and the "t" test. • Apply methods of the average values testing: calculating the standard error, the confidence interval and the "t" test. • • Properly select and use the parametric and nonparametric test of hypothesis testing, depending on the type and number of the compared values.	1. Standard error of relative values, confidence interval, significant difference between two relative values. 2. Standard error of average values, confidence interval, significant difference between two average values. 3. Non-parametric hypothesis tests: The χ^2 test, the Fisher test, the ANOVA tests, the Wilcoxon test.

Theme (chapter) 7. **Time Series and their Analysis.**

• List and describe the types of chronological series. • Adjust the chronological series by the methods: graphics, plain environments, sliding media. • Chronologically illustrate the chronological series. • Calculate the absolute, relative, and mean values of the chronological series.	1. The concept and peculiarities of time series. The types of time series. 2. Adjustment of time series: the meaning and methods of adjustment. 3. The analysis of time series: the calculation of absolute indicators. 4. The analysis of time series: the calculation of relative indicators 5. The graphical presentation of the time series.

Theme (chapter) 8. **Adjusted Rate: Direct Method of Standardization.**

• Define the standardization. • List and describe standardization methods. • Describe the stages of standardization by the direct method. • Explain the usefulness of applying standardization in medicine. • Apply the standardization method in comparing the statistical indicators.	1. Standardization in biostatistics. 2. Standardization methods: direct, indirect, tangential. 3. Standardization by direct method. Steps of standardization by direct method.

Theme (chapter) 9. **Correlation and Regression**

• Define correlation and regression. • Show different correlations. • Apply correlation coefficients in determining the correlation link type. • Describe the types of regression. • • Calculate the regression indicators.	1. Correlation - notion and function. Functional dependence and statistical correlation. Getting, features. 2. Studying correlations. Types of correlations and their assessment methodology. 3. Regression - notion and function. 4. Types of regression. Indicators of expression of regression types. 5. Linear regression. Characteristic. Calculation of regression indicators. Regression scale and its calculation.

Theme (chapter) 10. **Basic concepts of epidemiology and Study designs.**

• Define the basic notions of epidemiology. • List the fields of epidemiology application. • To name and describe various types of epidemiological investigations.	1. Definition and objectives of epidemiology. 2. The branches of epidemiology. 3. Basics notions and areas of epidemiology application. 4. Types of epidemiological surveys.

Theme (chapter) 11. **The Research Methodology Introduction. Preparing the Research Design.**

• Describe the stages of a scientific study. • Identify and describe a research problem. • Classify scientific studies. • Analyze various types of scientific studies.	1. Introduction to research methodology. Stages of research. 2. Problem of research: formulating the purpose and objectives of a research. 3. Classification and general presentation of epidemiological studies.

Theme (chapter) 12. **The Descriptive Studies**

• Define descriptive studies and describe their importance. • To characterize the particularities of descriptive studies. • Calculate the size of the sample for the descriptive study • Develop the design of a descriptive study. • Calculate the indicators of a descriptive study. • Describe the advantages and disadvantages of descriptive studies.	1. The essence and importance of descriptive studies. Objectives of descriptive studies. 2. Methods and sources of data collection in a descriptive study. 3. Comparisons in descriptive studies. Characteristics of types of descriptive studies. 4. The size of the representative sample for a descriptive study, its calculation and interpretation. 5. Stages of the descriptive study. The Advantages and Disadvantages of Descriptive Studies.

Theme (chapter) 13. **The Cohort Studies**

• Define cohort studies and describe their importance. • To characterize the peculiarities of cohort studies. • Calculate the size of the sample for the cohort study. • Develop the design of a cohort study. • Calculate the indicators of a cohort study. • List the advantages and disadvantages of cohort studies.	1. The essence of cohort studies. 2. Objectives, direction and sequencing of cohort studies. 3. Steps and issues in a cohort study. Indicators computed in a cohort study: relative risk, attributable risk, association strength. 4. The Advantages and Disadvantages of Cohort Studies.

Theme (chapter) 14. **The Case-Control Studies**

• Define case-control studies and describe their importance. • To characterize the particularities of case-control studies. • Calculate the sample size for the case-control study. • Develop the design of a case-control study. • Calculate the indicators of a case-control study. • • List the advantages and disadvantages of case-	1. The essence, objectives and particularities of the case-control studies. 2. Stages of case study - control. Specific and implementation difficulties. Flow Diagram. 3. The Advantages and Disadvantages of Case Studies - Control. 4. Calculation of indicators for case-control studie

control studies.	

Theme (chapter) 15. The Clinical Trials Studies

- Define, classify and describe the importance of clinical trials. - To characterize the particularities of randomized clinical trials. - Calculate the sample size for the randomized clinical trial. - Develop the design of a randomized clinical trial. - Calculate the indicators of a randomized clinical trial. • List the advantages and disadvantages of randomized clinical trials.	1. Specificity and scope of experimental epidemiological studies 2. Randomized clinical study, phases and phases 3. The Advantages and Disadvantages of Randomized Clinical Studies 4. Calculation of indicators for randomized clinical trials.

Theme (chapter) 16. Types of literature analysis. Critical evaluation of Scientific Researches

- To name and describe the types of literature analysis. - Describe the parts of an article. - To critically evaluate various scientific publications - Prepare an article for publication. - Make a correct list of the analyzed literature.	1. Literature review: importance, types. 2. Critical evaluation of the results of scientific research. 3. Summary and introductory part of a report or article. 4. Research Methods Section. 5. Result section and discussion. 6. Conclusions and compilation of the list of literature studied in a research.

Theme (chapter) 17. Reporting the Findings of the Research in Various Forms: Written, Graphic and Oral.

- List different ways of presenting statistical data. - Apply the chart type correctly depending on the analyzed indicator. - Be familiar with the requirements for drawing up tables and diagrams. - Know the requirements for the oral presentation of the research results and make a presentation of a research project.	1. Presentation of statistical data. 2. Table presentation. Table types and their feature 3. Graphic presentation. 4. Diagram building technologies. Classification of charts and their characteristics. 5. Requirements for oral presentation.

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

Professional (specific) (SC) competences

- PC4. Identification of types of statistical data and methods of analysis for understanding and describing demographic phenomena, morbidity and other processes in medicine and public health.
- PC5.Application of methods of testing of relative and average values and of parametric and nonparametric techniques in comparing the absolute, relative and central trend indicators.
- PC6. Define the basic concepts, theories, methods and principles regarding the collection, processing, analysis and interpretation of the information necessary for the professional activity.

Transversal competences (TC)

- TC1. Critical analysis of scientific literature and publications, and the application of principles of evidence-based medicine in practical work.
- TC2. Designing and conducting qualitative statistical study.
- TC3. Qualitative presentation of activity results and research results, taking into account the requirements for: elaboration of activity reports, writing of scientific articles, elaboration of the power point presentations, and public presentation of the obtained results.

At the end of the course Biostatistics and Reaserch Methodology the student will be able to:

- Apply different methods of collecting and processing primary data in a scientific study.
- Calculate the absolute, relative and central trend indicators.
- Apply methods to test the certainty of values.
- Apply parametric and nonparametric tests to compare absolute, relative or central trend values.
- Calculate and interpret the coefficient pf correlation for determining dependence between two or more phenomena.
- Design and calculate indicators for different types of studies: descriptive, case-control, cohort and randomized clinical trials.
- Organize a statistical survey, using the theoretical knowledge and practical skills obtained during the course study.
- Apply the knowledge gained in the discipline in the analysis of the personal practical activity, the results of the institution's activity, as well as the demographic and morbidity processes in the population.

VIII. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
1.	Case study analysis	The students will assigned the cases according to the themes studied. Studying supplementary literature, individually, students will solve and present	1. Correct resolution of the case. 2. The number of alternative solutions identified, 3. The degree of analysis	During the semester

		the case to the teacher	and the way to identify the optimal solution	
2.	Venn Chart	Analyzing basic and additional literature on topics related to various types of scientific studies, students would complete and present a Venn chart on similarities and differences between 4 types of studies.	1. Number of correct examples of similarities and differences between the analyzed scientific studies	The 14th week of study
3.	Critical analysis of two scientific articles	Students will individually select 2 articles published in medical journals to submit to the analysis.	1. Critical assessment of the validity and relevance of scientific research. 2. Number of gaps and mistakes in the structure and content of articles.	The 15th week of study
4.	The project of scientific research	Students will develop and present a scientific research project on a theme chosen by them individually.	1. How to apply the theoretical knowledge in the elaboration of the project. 2. Fairness and observance of the succession of the research stages. 3. Correct selection of type of study, research methods, representative sample volume, analysis methods, etc.	The 16th week of study

IX.   METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

• *Teaching and learning methods used*

   In the teaching process of the Biostatistics and Research Methodology discipline are used different didactic methods, oriented towards the efficient acquisition and achievement of the objectives of the didactic process. In the theoretical lessons, along with the traditional methods (lesson-exposure, lesson-conversation, synthesis lesson), modern methods (lesson-debate, lecture-conference, problematic lesson) are also used. In the practical lessons, forms of individual, frontal and group working are widely used.

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

Interactive lecture, guided discussion, demonstration, brainstorming, brainstorming, brain writing, group work, case study, Venn diagram, individual study, debate, problem solving.

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

Current: frontal and / or individual control through:

- case studies analysis.
- assessment tests application,
- control work- 2 test papers
- individual work assessment

Final: differential colloquium

The final mark will consist of the average score from 2 control papers and the mark at student's individual work (score-0.5),+ the final test (score-0.5).

The average annual mark and the marks of all the final colloquium stages (written form) - all will be expressed in numbers according to the scoring scale (according to the table) and the obtained final mark will be expressed in two decimal number being passed in the credit book.

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	E
5,51-6,0	6	E
6,01-6,50	6,5	D
6,51-7,00	7	D
7,01-7,50	7,5	C
7,51-8,00	8	C
8,01-8,50	8,5	B
8,51-8,00	9	B
9,01-9,50	9,5	A
9,51-10,0	10	A

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. Raevschi, Elena. Biostatistics & research methodology : methodological recommendation for medical students / E. Raevschi, D. Tintiuc ;. - Chisinau : Medicina, 2012 – 203 ex.
2. Etco C, Ferdohleb A., Social Medicine, -Chişinău, 2011, 121 p.
3. Spinei L., Lozan O., Badan V. Biostatistica. Chişinău, 2009, 186 p.
4. Spinei L., Ştefăneţ S. şi alţii. Epidemiologie şi metode de cercetare, Chişinău, 2006, 224 p.

B. Additional

1. Dawson Beth, Trapp Robert G., Basic &Clinical Biostatistics, USA, 2004, 438 p.
2. Gordis Leon, Epidemiology, USA, 2004, 335 p.
3. Daly B., Watt P.B., Treasure E., Essential Dental Public Health, Oxford, New York, 2006, 353.