National Technical University of Ukraine
"Igor Sikorsky Kyiv Polytechnic Institute"

Department of
Biomedical Engineering

# MEDICAL STATISTICS

## Working program of basic discipline (Syllabus)

| Requisites for basic discipline | |
|---|---|
| **Level of higher education** | ***First (bachelor's)*** |
| **Branch of knowledge** | *16 Chemical engineering and bioengineering* |
| **Specialty** | *163 Biomedical Engineering* |
| **Educational program** | *Medical Engineering* |
| **Discipline status** | *Elective discipline* |
| **Form of study** | *full-time* |
| **Year of preparation, semester** | *3th course, autumn semester* |
| **The scope of discipline** | *4 ECTS credits / 120 hours*<br>*(Lectures – 18 hours, Practical classes – 36 hours, Independent study – 66 hours)* |
| **Semester control / Control measures** | *Pass/fail test, term paper, modular test* |
| **Lessons schedule** | *https://schedule.kpi.ua/* |
| **Language of instruction** | *Ukrainian* |
| **Information about course leader / teachers** | ***Lecturer:*** *PhD in Engineering, Associate Professor, Associate Professor of the Department of Biomedical Engineering Oksana K. Biloshytska, e-mail: biloshytska.oksana@lll.kpi.ua*<br>***Practical Classes:*** *Assistant of the Department of Biomedical Engineering Ilona O. Matvieieva, e-mail: i.matveeva-fbmi@lll.kpi.ua* |
| **Course placement** | *Sikorsky Distance Learning Platform – Course: Medical Statistics (Course code: bf63ij)* |

## Curriculum of the discipline

### 1. Course Description, Purpose, Subject Area, and Learning Outcomes

***The main objective of the academic discipline "Medical Statistics"*** *is to develop in students a system of knowledge and practical skills related to the collection, preprocessing, statistical analysis, and interpretation of biomedical data required for scientifically grounded decision-making in the field of medicine and healthcare.*

*The discipline provides statistical training for future specialists aimed at the analysis of medical and biological data, evaluation of the results of clinical and epidemiological studies, testing of statistical hypotheses, and identification of relationships between health indicators.*

*Mastering the course is a necessary prerequisite for evidence-based medicine, scientific research, and the correct use of statistical analysis results in professional practice.*

***As a result of studying the academic discipline (educational component) "Medical Statistics", students are expected to acquire the following general competencies:***

*GC1. Ability to engage in abstract thinking, analysis, and generalization of quantitative information.*

*GC2. Ability to apply basic mathematical and statistical methods to solve applied problems.*

*GC3. Skills in working with information – collection, systematization, analysis, and critical evaluation of data.*

*GC4. Ability to make well-founded decisions based on quantitative analysis and statistical conclusions.*

***After mastering the academic discipline (educational component) "Medical Statistics", students are expected to possess the following special (professional) competencies:***

*PC1. Ability to apply methods of medical statistics for the analysis of biomedical and clinical data.*

*PC2. Ability to select and use appropriate statistical criteria for hypothesis testing in medical research.*

*PC3. Skills in assessing randomness and regularities in medical and biological processes.*

*PC4. Ability to analyze relationships between variables and interpret the results of correlation analysis in a medical context.*

***The program learning outcomes resulting from the study of the academic discipline (educational component) "Medical Statistics" are as follows:***

*PLO1. Ability to apply methods of medical statistics for the collection, grouping, and preprocessing of experimental and clinical biomedical data.*

*PLO2. Ability to select and correctly use statistical characteristics and measurement scales for the analysis of random variables in biomedical engineering systems.*

*PLO3. Ability to perform statistical hypothesis testing using parametric and non-parametric criteria and to interpret the results taking into account the engineering and medical context.*

*PLO4. Ability to investigate relationships between variables in biomedical data using correlation analysis and to formulate well-founded conclusions for solving applied engineering problems.*

***Contribution to the Educational Program Competencies***

*This course also contributes to the development of competencies and learning outcomes defined in the educational program approved by Rector's Order No. NON/434/24 dated June 10, 2024.*

***Integral Competency:*** *The ability to solve complex, specialized problems and practical problems in biomedical engineering and in the process, which provides the use of specific theories and methods of chemical, biological and medical engineering, and is characterized by the complexity and non-strict terms..*

***General Competencies***

*GC01 – Ability to apply knowledge in practical situations.*

*GC02 – Knowledge and understanding of the subject area and professional activity.*

*GC04 – Skills in using information and communication technologies.*

*GC06 – Ability to search for, process, and analyze information from various sources.*

*GC07 – Ability to generate new ideas (creativity).*

*GC08 – Ability to make reasoned decisions.*

***Professional Competencies***

*PC01 – Ability to apply engineering software packages for research, analysis, processing, and presentation of results, as well as for automated design of medical devices and systems.*

*PC03 – Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems.*

*PC05 – Ability to apply physical, chemical, biological, and mathematical methods in the analysis and modeling of the functioning of living organisms and biotechnical systems.*

*PC11 – Ability to develop, plan, and conduct experiments using specified technical and biomedical techniques, applying mathematical methods in the analysis and modeling of the functioning of living organisms, systems, and processes in biology and medicine, computer processing, analysis, and synthesis of the obtained results..*

***Program Learning Outcomes***

*PLO 05 - Be able to use databases, mathematical and software tools for data processing and*

*computer modeling of biotechnical systems.*

*PLO 20 - Knowledge and application of research methods in biomedical engineering, methods and tools for organizing and processing experimental data, statistical methods for modeling and simulating processes and systems of physical and biological nature, modern programming technologies and supporting tools, methods for designing digital and microprocessor-based medical systems.*

***Teaching Methods***

*Lectures are conducted using explanatory-illustrative methods, problem-based teaching, and interactive methods aimed at establishing dialogue with students.*

*Practical classes employ:*

1. *Reproductive method for consolidating theoretical knowledge and applying it to practical tasks.*
2. *Partially exploratory (heuristic) method to develop problem-solving strategies.*
3. *Interactive method to engage students in solving tasks and discussing theoretical foundations.*
4. *Presentation and discussion of results using problem-based and interactive approaches.*
5. *Mathematical modeling during practical sessions.*

*Students independently study literature and software tools for analysis and forecasting of medical data. In some cases, coursework may evolve into research activities.*

## 2. Prerequisites and Course Position in the Curriculum

*The course belongs to the elective component of the curriculum. Prerequisites include:*

*– **knowledge**: fundamentals of higher mathematics, in particular elements of mathematical analysis and linear algebra; basic concepts of probability theory (probability of an event, random variables, distributions); fundamentals of informatics and information technologies; principles of working with numerical data;*

*– **skills**: ability to perform elementary mathematical calculations and analyze numerical data; ability to apply algorithmic thinking to solve applied engineering problems; ability to use general-purpose software tools for data processing (spreadsheets, basic computational tools);*

*– **competencies**: skills in working with numerical information, including data entry, organization, and verification of data correctness; skills of independent learning and analytical work, as well as working with educational and reference literature; skills of logical analysis and interpretation of results required for further statistical generalization.*

## 3. Course Content

***Section 1. Fundamentals of Collection and Preprocessing of Biomedical Data***

*Topic 1.1. Purpose and objectives of the discipline*

*Topic 1.2. Sampling methods and grouping of primary data*

***Section 2. Regularity and Randomness***

*Topic 2.1. Measurement scales and random variables*

*Topic 2.2. Characteristics of random variables*

***Section 3. Hypothesis Testing for Location and Dispersion***

*Topic 3.1. Statistical hypothesis testing*

*Topic 3.2. Parametric criteria for testing hypotheses on differences*

*Topic 3.3. Non-parametric criteria for testing hypotheses on differences*

***Section 4. Relationships between Variables***

*Topic 4.1. Methods for studying relationships between system parameters and variables*

## 4. Training materials and resources

***Basic literature:***

1. *Огнєв, В. А., Помогайбо, К. Г., Трегуб, П. О., Усенко, С. Г., Пересипкіна, Т. В., Мартиненко, Н. М., … та ін. (2023). Соціальна медицина, громадське здоров'я: Біологічна статистика (Т. 1) [PDF]. Харків: ХНМУ. Доступно за адресою: https://www.scribd.com/document/831696716/ПОСІБНИК-БІОСТАТИСТИКА*
2. *Біостатистика засобами MS EXCEL. Частина 1 [Електронний ресурс] : навч. посіб. для здобувачів ступеня бакалавра за освітньою програмою «Регенеративна та біофармацевтична інженерія» спеціальності 163 Біомедична інженерія / КПІ ім. Ігоря Сікорського ; Мулик О. В., Пригалінська Т. Г., Свистун-Золотаренко Л. О - Київ : КПІ ім. Ігоря Сікорського, 2023. - 364 с. – Режим доступу: https://ela.kpi.ua/handle/123456789/57312*
3. *Петровська, І. Р., Салига, Ю. Т., & Вудмаска, І. В. (2022). Статистичні методи в біологічних дослідженнях: Навчально-методичний посібник [PDF]. Київ: Аграрна наука. Доступно за адресою: https://www.inenbiol.com/images/stories/Rozrobky/Books/2022/Statistika_2022.pdf*

***Additional literature:***

1. *IBM SPSS Statistics 26 documentation. – Режим доступу: https://www.ibm.com/docs/en/spss-statistics/26.0.0*
2. *Гур'янов, В. Г., Лях, Ю. Є., Парій, В. Д., & Короткий, О. В. (2021). Посібник з біостатистики: Аналіз результатів медичних досліджень у пакеті EZR (R-statistics) [PDF]. Доступно за адресою: Біостатистика: Підручники | СЕЗН.ЗНУ*
3. *Статистика [Електронний ресурс] : навчальний посібник / О. В. Раєвнєва, І. В. Аксьонова, О. І. Бровко ; за заг. ред. д-ра екон. наук, професора О. В. Раєвнєвої. – Харків : ХНЕУ ім. С. Кузнеця, 2019. – 389 с. – Режим доступу: http://repository.hneu.edu.ua/bitstream/123456789/24523/1/2019%20-%20%D0%A0%D0%B0%D1%94%D0%B2%D0%BD%D1%94%D0%B2%D0%B0%20%D0%9E%20%D0%92.pdf*
4. *Голованова І. А. Основи медичної статистики : навч. посіб. для аспірантів та клінічних ординаторів / І. А. Голованова, І. В. Бєлікова, Н. О. Ляхова. – Полтава, 2017. – 113 с. Режим доступу: https://repository.pdmu.edu.ua/handle/123456789/10614*
5. *Методичні вказівки до виконання комп'ютерних практикумів з навчальної дисципліни «Медична інформатика і кібернетика – 5. Математичне моделювання та симуляція біомедичних систем» для студентів спеціальності 163 «Біомедична інженерія» [Електронний ресурс] / КПІ ім. Ігоря Сікорського ; уклад.: Є. А. Настенко, В. А. Павлов, О. К. Носовець, В. С. Якимчук. – Київ : КПІ ім. Ігоря Сікорського, 2017. – 115 с. – Режим доступу: https://ela.kpi.ua/handle/123456789/19932.*
6. *Мінцер О.П. та ін. Інформаційні технології в охороні здоровя і практичній медицині: У 10 кн. Кн. 5. Оброблення клінічних і експериментальних даних в медицині: Навч. Посіб. / О.П. Мінцер, Ю.В. Вороненко, В.В. Власов. - К.: Вищ. Пік., 2003. - 350 с.*

## Educational content

### 5. Methods of mastering the discipline (educational component)

| *No.* | *Lecture Title and Key Topics (teaching and learning methods, independent study tasks)* | *General, Professional Competencies and Program Learning Outcomes* |
|---|---|---|
| *Lecture 1* | ***Medical statistics as a scientific discipline*** | ***GC1, GC3;PC1;PLO1*** |

| No. | Lecture Title and Key Topics (teaching and learning methods, independent study tasks) | General, Professional Competencies and Program Learning Outcomes |
|---|---|---|
| | ***Key issues:*** *Subject, purpose and objectives of medical statistics. The role of statistics in biomedical engineering and evidence-based medicine. Types of statistical studies in medicine and biomedicine. Stages of a statistical study.*<br>***Didactic tools:*** *multimedia presentation; diagrams of statistical analysis stages; examples of biomedical studies.*<br>***Independent study:*** *study the concepts of "evidence-based medicine" and "biostatistics"; prepare a short summary of the stages of a statistical study.* | |
| ***Lecture 2*** | ***Sampling methods in medical and biological research***<br><br>***Key issues:*** *General population and sample. Sampling methods. Sample representativeness and errors. Sample size and its significance.*<br>***Didactic tools:*** *multimedia presentation; tables of sampling types; examples of samples in clinical studies.*<br>***Independent study:*** *conduct a comparative analysis of sampling types; provide examples of correct and incorrect sample formation.* | ***GC1, GC2, GC3;PC1, PC3;PLO1*** |
| ***Lecture 3*** | ***Primary medical data and their grouping***<br><br>***Key issues:*** *Sources of primary biomedical data. Qualitative and quantitative data. Data grouping and construction of statistical series. Tabular and graphical presentation of data.*<br>***Didactic tools:*** *multimedia presentation; examples of tables and histograms; demonstration of datasets*<br>***Independent study:*** *group the proposed dataset; construct a frequency table.* | ***GC2, GC3;PC1, PC3;PLO1*** |
| ***Lecture 4*** | ***Measurement scales and random variables***<br><br>***Key issues:*** *Concept of measurement scale. Nominal, ordinal, interval and ratio scales. Random variable and its types. Importance of scale selection for statistical analysis.*<br>***Didactic tools:*** *multimedia presentation; examples of biomedical variables; comparative tables of scales.*<br>***Independent study:*** *classify biomedical indicators according to measurement scales.* | ***GC1, GC2;PC3;PLO2*** |
| ***Lecture 5*** | ***Characteristics of random variables***<br><br>***Key issues:*** *Measures of central tendency. Measures of dispersion. Variability and its biomedical significance. Normal distribution and its properties.*<br>***Didactic tools:*** *multimedia presentation; distribution graphs; calculation examples.*<br>***Independent study:*** *calculate basic statistical characteristics for a given dataset.* | ***GC1, GC2, GC4;PC3;PLO2*** |
| ***Lecture 6*** | ***Statistical hypotheses and principles of their testing***<br><br>***Key issues:*** *Concept of a statistical hypothesis. Null and alternative hypotheses. Significance level and statistical error. General algorithm for hypothesis testing.*<br>***Didactic tools:*** *multimedia presentation; algorithm flowcharts; examples of hypotheses in medicine.*<br>***Independent study:*** *formulate null and alternative hypotheses for a given task.* | ***GC1, GC4;PC2;PLO3*** |
| ***Lecture 7*** | ***Parametric criteria for hypothesis testing*** | ***GC2, GC4;PC2;PLO3*** |

| No. | Lecture Title and Key Topics (teaching and learning methods, independent study tasks) | General, Professional Competencies and Program Learning Outcomes |
|---|---|---|
| | ***Key issues:*** *Assumptions for the use of parametric methods. Student's t-test. Analysis of variance. Analysis of differences between mean values. Interpretation of parametric test results.*<br>***Didactic tools:*** *multimedia presentation; calculation examples; tables of critical values.*<br>***Independent study:*** *analyze an example of applying the t-test and analysis of variance in a biomedical study.* | |
| ***Lecture 8*** | ***Non-parametric criteria for hypothesis testing***<br><br>***Key issues:*** *Limitations of parametric methods. Main non-parametric criteria. Comparison of parametric and non-parametric approaches. Fields of application in biomedical engineering.*<br>***Didactic tools:*** *multimedia presentation; comparative tables; examples of tasks.*<br>***Independent study:*** *justify the choice of a non-parametric criterion for a given situation.* | ***GC2, GC4;PC2;PLO3*** |
| ***Lecture 9*** | ***Analysis of relationships between variables***<br><br>***Key issues:*** *Concept of statistical relationship. Correlation analysis and its types. Interpretation of correlation coefficients. Limitations of correlation analysis.*<br>***Didactic tools:*** *multimedia presentation; scatter plots; examples of biomedical data.*<br>***Independent study:*** *construct a correlation diagram and interpret the obtained result.* | ***GC1, GC4;PC4;PLO4*** |

| No. | Title of the class and list of key issues (teaching aids, independent study tasks) | GC, PC and PLO according to the Educational Program |
|---|---|---|
| ***Practical class 1*** | ***Organization and stages of statistical analysis of biomedical data***<br><br>***Key issues:*** *structure of a statistical study; stages of data collection and analysis; role of statistics in biomedical engineering.*<br>***Didactic tools:*** *computer, presentation materials, examples of biomedical studies.*<br>***Independent study:*** *studying the stages of a statistical study and their purpose.* | ***GC1, GC3;PC1;PLO1*** |
| ***Practical class 2*** | ***Practical work No. 1. Development of a biomedical research plan***<br><br>***Key issues:*** *formulation of research objectives and tasks; definition of the object, subject, and variables; selection of statistical analysis methods.*<br>***Didactic tools:*** *computer, research plan template, examples of scientific publications.*<br>***Independent study:*** *preparation of a written biomedical research plan.* | ***GC1, GC3, GC4;PC1;PLO1*** |
| ***Practical class 3*** | ***Defense of practical work No. 1****.*<br>***Sampling methods in biomedical research*** | ***GC1, GC2, GC3;PC1,*** |

| | | |
|---|---|---|
| | ***Key issues:*** *population and sample; types of samples; representativeness and sampling errors.*<br>***Didactic tools:*** *computer, educational datasets, tables.*<br>***Independent study:*** *analysis of examples of sample formation.* | ***PC3;PLO1*** |
| ***Practical class 4*** | ***Primary biomedical data and their preparation for analysis***<br><br>***Key issues:*** *types of primary data; coding and data validation; preparation of data for statistical processing.*<br>***Didactic tools:*** *computer, spreadsheets, sample datasets.*<br>***Independent study:*** *preparation of a primary dataset for analysis.* | ***GC2, GC3;PC1, PC3;PLO1*** |
| ***Practical class 5*** | ***Practical work No. 2. Determination of basic statistical indicators (Part 1)***<br><br>***Key issues:*** *measures of central tendency; measures of variability; analysis of dispersion of biomedical data.*<br>***Didactic tools:*** *computer, data analysis software environment, educational datasets.*<br>***Independent study:*** *calculation of statistical characteristics for a given sample.* | ***GC1, GC2;PC3;PLO2*** |
| ***Practical class 6*** | ***Practical work No. 2. Construction of statistical graphs and diagrams (Part 2)***<br><br>***Key issues:*** *histograms; distribution polygons; scatter plots; rules for visualization of biomedical data.*<br>***Didactic tools:*** *computer, visualization software tools, sample graphs.*<br>***Independent study:*** *construction and interpretation of statistical graphs.* | ***GC2, GC3, GC4;PC1;PLO1, PLO2*** |
| ***Practical class 7*** | ***Defense of practical work No. 2.***<br>***Measurement scales of biomedical indicators. Random variables and statistical distributions***<br><br>***Key issues:*** *nominal, ordinal, interval, and ratio scales; influence of scale on the choice of statistical methods; types of random variables; normal distribution; assessment of data distribution characteristics.*<br>***Didactic tools:*** *computer, comparative tables, examples of variables, distribution graphs, educational datasets.*<br>***Independent study:*** *classification of biomedical indicators by measurement scales; analysis of biomedical data distributions.* | ***GC1, GC2;PC3;PLO2*** |
| ***Practical class 8*** | ***Practical work No. 3. Statistical hypotheses and their testing algorithm***<br><br>***Key issues:*** *null and alternative hypotheses; significance level; statistical decision errors.*<br>***Didactic tools:*** *computer, algorithm diagrams, example tasks.*<br>***Independent study:*** *formulation of statistical hypotheses for a given situation.* | ***GC1, GC4;PC2;PLO3*** |
| ***Practical class 9*** | ***Defense of practical work No. 3***<br>***Practical work No. 4. Application of Student's t-test***<br><br>***Key issues:*** *conditions for applying the t-test; comparison of mean values; interpretation of results.* | ***GC2, GC4;PC2;PLO3*** |

| | | |
|---|---|---|
| | ***Didactic tools:*** *computer, data analysis software environment, tables of critical values.*<br>***Independent study:*** *performing t-test calculations for educational data.* | |
| ***Practical class 10*** | ***Defense of practical work No. 4***<br>***Analysis of differences between samples***<br><br>***Key issues:*** *logic of comparative analysis; selection of statistical criteria; interpretation of results.*<br>***Didactic tools:*** *computer, examples of biomedical tasks.*<br>***Independent study:*** *justification of the choice of a method for analyzing differences.* | ***GC2, GC4;PC2;PLO3*** |
| ***Practical class 11*** | ***Practical work No. 5. Analysis of variance of biomedical data***<br><br>***Key issues:*** *concept of variance; one-way analysis of variance; interpretation of results.*<br>***Didactic tools:*** *computer, data analysis software environment, educational datasets.*<br>***Independent study:*** *performing analysis of variance for a given sample.* | ***GC2, GC4;PC2, PC3;PLO3*** |
| ***Practical class 12*** | ***Defense of practical work No. 5***<br>***Practical work No. 6. Non-parametric criteria for independent samples***<br><br>***Key issues:*** *criteria for comparison of independent samples; interpretation of statistical results.*<br>***Didactic tools:*** *computer, data analysis software environment, example tasks.*<br>***Independent study:*** *solving problems using non-parametric criteria.* | ***GC2, GC4;PC2;PLO3*** |
| ***Practical class 13*** | ***Defense of practical work No. 6***<br>***Practical work No. 7. Non-parametric criteria for dependent samples***<br><br>***Key issues:*** *analysis of paired observations; criterion selection; interpretation of results.*<br>***Didactic tools:*** *computer, educational biomedical datasets.*<br>***Independent study:*** *performing analysis of dependent samples.* | ***GC2, GC4;PC2;PLO3*** |
| ***Practical class 14*** | ***Defense of practical work No. 7***<br>***Practical work No. 8. Correlation analysis of biomedical data***<br><br>***Key issues:*** *concept of correlation; correlation coefficients; interpretation of relationships between variables.*<br>***Didactic tools:*** *computer, data analysis software environment, scatter plots.*<br>***Independent study:*** *performing correlation analysis for given data.* | ***GC1, GC4;PC4;PLO4*** |
| ***Practical class 15*** | ***Defense of practical work No. 8*** | ***GC4;PC4;PLO4*** |
| ***Practical class 16*** | ***Generalization and interpretation of statistical analysis results***<br><br>***Key issues:*** *presentation of results; formulation of statistical conclusions; typical interpretation errors.*<br>***Didactic tools:*** *computer, examples of reports and scientific articles.*<br>***Independent study:*** *preparation of an analytical conclusion based on analysis results.* | ***GC1, GC4;PC1, PC4;PLO1–PLO4*** |

| | | |
|---|---|---|
| ***Practical class 17*** | ***Module assessment***<br><br>***Key issues:*** *assessment of mastery of theoretical and practical provisions of the discipline.*<br>***Didactic tools:*** *assessment tasks, module test variants.*<br>***Independent study:*** *revision of learning materials and preparation for assessment.* | ***GC1–GC4;PC1–PC4;PLO1–PLO4*** |
| ***Practical class 18*** | ***Generalization and preparation for the final assessment***<br><br>***Key issues:*** *revision of key methods; analysis of typical errors.*<br>***Didactic tools:*** *presentation materials, sample tasks.*<br>***Independent study:*** *revision of learning materials.* | ***GC1–GC4;PC1–PC4;PLO1–PLO4*** |

## 6. Student Independent Study

*Preparation for classroom activities – 45 hours*
*Preparation for the modular control test – 4 hours*
*Completion of the individual semester assignment – 11 hours*
*Preparation for the pass/fail test – 6 hours*

***Types of Student Activities and Estimated Time Allocation***

| ***Type of student activity*** | ***Estimated time (hours)*** |
|---|---|
| *Preparation for 1 hour of lectures* | *0.5* |
| *Preparation for 1 hour of practical classes* | *1.0* |
| *Preparation for the modular control test* | *4* |
| *Preparation for the pass/fail test* | *6* |
| *Individual semester assignment (term paper / report)* | *11* |

*One of the main forms of semester assessment during the study of the course **"Medical Statistics"** is the preparation of a **term paper (report)**. The term paper is completed during the semester, formatted according to the established requirements, and submitted for assessment during the **15th practical class**.*

*A term paper is a **scientific and technical document** that contains comprehensive and systematized information on a selected topic. It involves the presentation of material based on specially selected literature and independently conducted research. A student may prepare a term paper **only on a topic approved by the instructor**.*

***General requirements for the term paper:***

- *clarity and logical consistency of the presentation;*
- *persuasiveness of arguments;*
- *conciseness and precision of formulations that exclude ambiguous interpretation;*
- *specificity in presenting research results;*
- *justification of recommendations and proposals.*

***The term paper must address:***

- *the relevance of the topic and its correspondence to the current state of science, technology, and production-related issues;*
- *justification of the chosen research direction and problem-solving methods, including their comparative evaluation;*
- *analysis and generalization of existing research results;*
- *development of a general research methodology;*
- *the nature and content of performed theoretical studies and calculations, research methods applied;*

- *justification of the need for experimental studies, principles of operation of developed software tools, their characteristics, evaluation of calculation errors, and obtained experimental data;*
- *assessment of the completeness of solving the stated problem;*
- *evaluation of the reliability of obtained results and their comparison with analogous results;*
- *scientific and practical value of the completed work.*

***Structure of the term paper:***

*title page; table of contents; list of symbols, abbreviations, and terms (if necessary); introduction; main body; conclusions; list of references; appendices (if necessary).*

***Approximate list of term paper topics:***

1. *The role of medical statistics in biomedical engineering and evidence-based medicine.*
2. *Stages of statistical analysis of biomedical data: from data collection to interpretation of results.*
3. *Sampling methods in clinical and biomedical research: principles and limitations.*
4. *Sample representativeness and statistical errors in medical research.*
5. *Measurement scales of biomedical indicators and their influence on the choice of statistical methods.*
6. *Random variables in medical and biological processes and their statistical characteristics.*
7. *Measures of central tendency and dispersion in the analysis of biomedical data.*
8. *The normal distribution and its significance for the analysis of medical indicators.*
9. *Statistical hypotheses in medical research: formulation and testing.*
10. *Parametric hypothesis testing criteria in biomedical engineering.*
11. *Non-parametric methods of statistical analysis of biomedical data.*
12. *Comparative analysis of parametric and non-parametric statistical criteria.*
13. *Analysis of variance in biomedical research: capabilities and limitations.*
14. *Correlation analysis in the study of relationships between biomedical indicators.*
15. *Interpretation of correlation coefficients in medical and bioengineering research.*
16. *Typical errors of statistical analysis in medical publications.*
17. *Use of software tools for statistical analysis of biomedical data.*
18. *Statistical processing of experimental data in biomedical engineering.*
19. *Visualization of biomedical data as a means of enhancing the informativeness of analysis.*
20. *The importance of medical statistics for engineering decision-making in healthcare.*

***Title page requirements:***

*The title page of the term paper must include: the name of the university; the name of the faculty; the name of the department; the name of the specialty; the name of the educational program; the name of the course; the title of the term paper; the student's first and last name; year of study; academic group number; and the year of completion.*

*Following the title page, a list of abbreviations (if necessary) and a detailed table of contents must be provided. The table of contents should clearly identify the introduction, sections of the main body (main topics to be considered), subsections (if necessary), conclusions, and the list of references. Page numbers indicating the beginning of each section must be aligned on the right. Each section must begin on a new page.*

*The total length of the term paper, depending on the selected topic, may range from **25 to 40 pages of the main text** (subject to agreement with the instructor). The length is determined by the student's ability to concisely and comprehensively explain and analyze the obtained information.*

***Mandatory requirements:***

*All sources of information must be clearly referenced. All numerical data, facts, scientific opinions, quotations, and formulas must include references in the form **[2]**, where the number corresponds to the source in the reference list at the end of the paper. Tables, schemes, graphs, diagrams, and other visual*

*materials must be used.*

*The list of references must contain **at least 10 sources** and be formatted according to the **APA citation style**. All sources must have been published within the **last 5 years**. Preference is given to **foreign (international) sources**. If information is obtained from the Internet, the author, title of the article, and the website address must be indicated, as for printed sources.*

***Assessment criteria:***

*The term paper is evaluated based on the following criteria: logical structure of the outline; completeness and depth of topic coverage; reliability of obtained data; inclusion of practical materials; correctness of conclusions and final results; quality of formatting; justification of the student's own viewpoint in the conclusions.*

***Submission deadline:***

*The final deadline for submitting the term paper for assessment is the **15th practical class**.*

*The term paper is **not checked for plagiarism**, but it must comply with the principles of **academic integrity**. In cases of academic misconduct, the paper is annulled and not assessed.*

## Policy and Assessment

### 7. Course Policy (Educational Component)

***Attendance***

*Attendance at **practical classes is mandatory**, as these classes include short in-class assessments / test tasks, as well as the completion and defense of practical works. A student is required to be present for the **entire duration of the class**, from the beginning to the end, and to actively participate in the learning process.*

*Attendance at **lectures is not mandatory**.*

*In case of justified absence (illness, official circumstances), the student must inform the instructor in advance or as soon as possible and **make up for the missed class** in accordance with the established procedure.*

***Rules of Conduct During Classes***

*Students are required to adhere to the principles of **academic ethics** and mutual respect toward the instructor and other students.*

*Active participation is encouraged during classes, including answering questions, participating in discussions, and completing learning tasks.*

*If necessary, students may prepare short oral or written presentations, reports, or analytical texts related to the course topics.*

*Mobile phones and other personal communication devices must be switched off or set to silent mode.*

*The use of laptops, tablets, and mobile devices is permitted **exclusively for educational purposes**, such as completing practical tasks, searching for materials on relevant educational platforms, in open-access sources, or working with educational datasets.*

***Missed Assessment Activities***

*Missed assessment activities (defense of practical works) must be completed during subsequent classes, provided that the task planned for the current class has been completed, or during scheduled consultations.*

*Missing the **modular control test** or short in-class assessments / test tasks is **not permitted**. A term paper submitted **after the established deadline** is **not assessed**.*

***Rules for the Defense of Practical Works***

*A practical work is considered completed provided that the results are submitted on time and **successfully defended orally**.*

*The defense of a practical work includes: explanation of problem-solving methods; interpretation of obtained results; and answering the instructor's questions.*

*Works completed in violation of the principles of **academic integrity** (plagiarism, copying, use of others' results without proper referencing) are **not admitted for defense and are not assessed**.*

***Deadline and Retake Policy***

*All types of academic work (practical works, term paper, modular control test) must be completed within the deadlines specified in the syllabus.*

*Late submission of assignments without a valid reason may result in **refusal to assess the work**.*

*In the presence of justified reasons, a student has the right to **individually agree on a new submission deadline** with the instructor.*

*Retaking assessment activities is carried out in accordance with the regulations, orders, and instructions of **Igor Sikorsky Kyiv Polytechnic Institute**.*

***Bonus Points***

*Bonus points may be awarded for creative academic activities related to the course (e.g., participation in academic competitions, conferences, scientific contests, preparation of reviews of scientific works or publications, etc.). These bonus points **do not form part of the standard grading scale**.*

*The total number of bonus points **may not exceed 10 points**, and the overall student rating **may not exceed 100 points**.*

***Academic Integrity***

*The policy and principles of academic integrity are defined in **Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute"**. More details are available at: https://kpi.ua/code*

***Ethical Standards of Conduct***

*The standards of ethical conduct for students and staff are defined in **Section 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute"**. More details are available at: https://kpi.ua/code*

***Procedure for Appealing Assessment Results***

*Students have the right to raise any issues related to assessment procedures and may expect them to be reviewed in accordance with predefined procedures.*

*A student has the right to appeal the results of an assessment activity in accordance with the approved **Regulation on Appeals at Igor Sikorsky Kyiv Polytechnic Institute** (approved by Order No. NON/128/2021 dated May 20, 2021): https://osvita.kpi.ua/index.php/node/182*

***Inclusive Education***

*The course "Medical Statistics" may be delivered to most students with special educational needs, except for students with severe visual impairments that prevent them from performing tasks using personal computers, laptops, and/or other technical devices.*

***Distance Learning***

*Distance learning is conducted via the **"Sikorsky" Distance Learning Platform**.*

*Distance learning through additional online courses on specific topics is allowed subject to agreement with students. If only a small number of students express a desire to complete an online*

*course on a particular topic, studying the material through such courses is permitted; however, students must complete **all assignments предусмотрені by the course syllabus**.*

*The list of available courses is proposed by the instructor after students express their interest, as the pool of available courses is updated almost monthly.*

*The student must provide a document confirming completion of the online course (in case of completing the full course) or submit completed practical tasks from the online course. Upon successful completion of an oral interview with the instructor on the studied topics, the student may receive grades for the assessment activities предусмотрені for the relevant topics (short assessments / test tasks, practical works).*

*Practical works and the term paper are completed during students' **independent study in a distance-learning format**, with the possibility of consultations with the instructor via email or social networks.*

***Instruction in a Foreign Language***

*Instruction in English is provided **only for international students**.*

*At the request of students, studying course materials through English-language online courses corresponding to the topics of specific classes is permitted.*

## 8. Types of Assessment and the Rating-Based Grading System (RGS)

*The assessment system is focused on awarding points for student engagement and for completing tasks aimed at developing practical skills and competencies.*

***Assessment System (Continuous Assessment)***

| No. | Assessment component | % | Weight (points) | Quantity | Total |
|---|---|---|---|---|---|
| 1 | Short in-class assessments / test tasks | 18 | 2 | 9 | 18 |
| 2 | Completion and defense of practical works | 56 | 7 | 8 | 56 |
| 3 | Modular control test | 12 | 12 | 1 | 12 |
| 4 | Term paper (report) | 14 | 14 | 1 | 14 |
| 5 | Pass/Fail assessment work[1] | 86 | 86 | 1 | 86 |
| | **Total** | **100** | | | **100** |

*[1] The result is counted toward the overall rating together with the term paper grade if the student has earned fewer than 60 points during the semester or wishes to improve the final grade.*

*Failure to complete a continuous assessment activity **in synchronous mode without a valid reason** is graded **0 points**.*

***Rules for Assessing the Completion and Defense of Practical Works***

- *Each practical work is graded on a **7-point rating scale**.*
- *The **maximum score** for one practical work is **7 points**.*
- *The **minimum passing threshold** is **at least 60%** of the maximum score, which corresponds to **5 points**.*
- *A result below the threshold (**less than 5 points**) is considered **unsatisfactory** and is graded **0 points**.*

***Criteria for Assessing a Practical Work***

| Criterion | Maximum points |
|---|---|
| Correctness of calculations and modeling | 3 |
| Justification of selected methods and models | 2 |
| Analysis and interpretation of results | 1 |
| Oral defense and answers to questions | 1 |
| **Total** | **7** |

***Conditions for Passing a Practical Work***

- *A practical work is considered passed if the student scores **5–7 points**.*
- *If **0 points** are awarded, the work **cannot be revised or re-defended** during the academic debt remediation period.*
- *Works completed in violation of **academic integrity principles** are **not accepted** and are graded **0 points**.*

***Rules for Assessing the Term Paper***

- *The term paper is graded on a **14-point rating scale**.*
- *The **maximum score** for the term paper is **14 points**.*
- *The **minimum passing threshold** is **at least 60%**, which corresponds to **9 points**.*
- *A term paper graded **below 9 points** is considered **not passed** and is graded **0 points**.*

***Criteria for Assessing the Term Paper***

| Criterion | Maximum points |
|---|---|
| Relevance to the topic and completeness of coverage | 4 |
| Correct application of mathematical models and methods | 4 |
| Independence of analysis and soundness of conclusions | 5 |
| Quality of formatting and compliance with academic integrity | 1 |
| **Total** | **14** |

***Conditions for Passing the Term Paper***

- *A term paper is considered passed if the student scores **9–14 points**.*
- *If **0 points** are awarded, the student must **revise the paper and resubmit it** before the start of the academic debt remediation period.*
- *Detection of plagiarism or other violations of **academic integrity** results in a grade of **0 points**.*

***Pass/Fail Assessment and Application of the Rating System***

*Students who have met all eligibility requirements for the pass/fail assessment and have accumulated **60 or more points** receive the corresponding rating grade **without completing an additional semester assessment**.*

*For students who have met all eligibility requirements but have a rating score **below 60 points**, as well as for those who wish to **improve their rating**, the instructor conducts a semester assessment during the examination week in the form of a **pass/fail test or an oral interview**.*

*After completing the pass/fail assessment:*

- *if the score obtained in the pass/fail assessment is **higher** than the accumulated rating, the student receives the **pass/fail assessment score**;*
- *if the score obtained is **lower** than the accumulated rating, a **"strict" Rating-Based Grading System** is applied: the student's previous rating (excluding points for the individual semester assignment) is annulled, and the final grade is determined **solely based on the pass/fail assessment result**.*

*This approach fosters a **responsible attitude** toward the decision to undertake the pass/fail assessment, encourages students to **critically evaluate their level of preparedness**, and motivates thorough preparation for the final assessment.*

***Calendar Control (CC)***

*Calendar Control (CC) is conducted **twice per semester** as a monitoring tool to assess the current status of compliance with the syllabus requirements.*

*The purpose of Calendar Control is to **improve the quality of student learning** and to **monitor students' adherence to the academic schedule**.*

***Calendar Control Criteria***

| Criterion | First CC | Second CC |
|---|---|---|
| **Timing of calendar control** | Week 7 | Week 13 |
| **Conditions for obtaining a positive result** | | |
| Current rating | ≥ 13 points | ≥ 31 points |
| Completion of practical works: PW No. 1–3 | + | + |
| Completion of practical works: PW No. 4–7 | – | + |
| Short in-class assessments / test tasks: minimum for any 2 lectures | + | – |

| | | |
|---|---|---|
| *Short in-class assessments / test tasks: minimum for any 6 lectures* | *–* | *+* |
| *Modular control test (graded)* | *–* | *–* |
| *Term paper (graded)* | *–* | *–* |

*In case of detection of **academic misconduct** during the learning process, the corresponding assessment activity **is not credited**.*

***Semester Assessment: Pass/Fail Test***

***Eligibility Requirements for Semester Assessment***

*Admission to the semester assessment (pass/fail test) requires **no outstanding academic debts** in practical works and the individual semester assignment (term paper), as well as **completion of the modular control test**.*

***Mandatory Eligibility Requirements***

| No. | Requirement | Criterion |
|---|---|---|
| 1 | Current rating | RD ≥ 40 |
| 2 | Positive grade for the term paper | More than 9 points |
| 3 | All practical works completed and defended | More than 40 points |
| 4 | Modular control test completed | More than 7 points |

***Optional Eligibility Requirements***

1. *Positive results in the **first and second Calendar Controls**.*
2. *Attendance of lecture classes.*

***Conversion of Rating Points to Grades (University Grading Scale)***

| Number of points | University grade |
|---|---|
| 95–100 | Excellent |
| 85–94 | Very good |
| 75–84 | Good |
| 65–74 | Satisfactory |
| 60–64 | Pass |
| Less than 60 | Fail |

## 9. Additional Course Information (Educational Component)

*The list of questions for preparation for the **modular control test** as well as for preparation for the **pass/fail assessment** is provided in **Appendix 1**.*

*Distance learning through the completion of additional **online courses** on specific topics is permitted subject to agreement with students. In cases where only a limited number of students express a desire to complete an online course on a particular topic, studying the material through such courses is allowed; however, students are required to complete **all assignments by the course syllabus**.*

*The list of recommended courses is proposed by the instructor after students express their interest, as the pool of available courses is updated almost monthly.*

*The student must provide a document confirming completion of the distance course (in the case of completing the full course) or submit completed practical assignments from the distance course. Upon successful completion of an **oral interview with the instructor** on the studied topics, the student may receive grades for the assessment activities provided for the relevant topics (short in-class assessments / test tasks, practical works).*

*In the event of the introduction of an **asynchronous learning mode**, the deadlines for completing assessment activities may be adjusted.*

***Course Syllabus***

*The course syllabus was prepared by Associate Professor of the Department of Biomedical Engineering, PhD in Engineering, Associate Professor Oksana Biloshytska, and Assistant of the Department of Biomedical Engineering Ilona Matvieieva.*

***Approved by** the Department of Biomedical Engineering (protocol № 16 of June 21, 2024)*

***Approved by** the Methodical Commission of the Faculty of Biomedical Engineering (protocol № 9 of June 26, 2024)*

## *List of Questions for Preparation for the Modular Control Test*

*and for the Pass/Fail Assessment*

1. *Characterize the concepts of statistics, medical statistics, and statistical methods, as well as population and sample. Identify their similarities and differences.*
2. *Where are statistical methods applied? Provide examples.*
3. *What is data analysis? How do observations, variables, variable values, and variable distributions differ from each other?*
4. *What is meant by the term "data"? Identify, characterize, and provide examples of different types of data.*
5. *Characterize the normal distribution of data.*
6. *State and explain the "two-sigma" and "three-sigma" rules.*
7. *Identify and characterize the stages of a statistical study.*
8. *Identify and characterize measures of central tendency, measures of dispersion (variance), and measures of frequency distribution of a variable.*
9. *Identify the main types of measurement scales used in statistics and provide examples.*
10. *Characterize the range, quartiles, percentiles, as well as distribution moments and shape measures.*
11. *Characterize the standard error of the mean and the coefficient of variation.*
12. *Characterize the frequency polygon, cumulative frequency curve, ogive, bar chart, pie chart, histogram, and line graph. Name additional graphs used for presenting statistical data and indicate what they display.*
13. *State the main conclusions of the central limit theorem. What is a confidence interval? How is it calculated?*
14. *Characterize the Student's t-distribution and the Poisson distribution.*
15. *Characterize and provide examples of a hypothesis, a statistical hypothesis, a null hypothesis, and an alternative hypothesis.*
16. *Hypothesis testing in statistics (table). Type I and Type II errors. Provide examples. Present the general scheme of hypothesis testing.*
17. *Characterize statistical methods according to the number of variables, statistical principles underlying the methods, the possibility of accounting for prior assumptions, and dependence or independence of the compared samples.*
18. *Capabilities and limitations of parametric and non-parametric tests.*
19. *What requirements are imposed on experimental data when using parametric and non-parametric tests?*
20. *The method of comparing means. What is its purpose?*
21. *Identify the types of t-tests and indicate the key aspects of each.*
22. *The Student's t-test and t-distribution: purpose and interpretation of the t-statistic.*
23. *Dependent and independent variables. Provide examples.*
24. *What is analysis of variance (ANOVA)? Identify its advantages and disadvantages. Specify the main tasks solved using ANOVA.*
25. *Identify the main terms and present the basic scheme of analysis of variance.*
26. *Analysis of covariance, multiple comparisons, and repeated-measures analysis of variance.*
27. *One-way and multi-way analysis of variance: definitions and applications. One-way ANOVA model.*
28. *Fisher's criterion (F-test). What is its purpose?*
29. *Provide three formulas for the sum of squares. Factor (between-group) and residual (within-group) variance.*

30. *What are covariates used for? Variance. Decomposition of total variance. Multiple correlation.*
31. *Types of interactions (provide graphs and indicate types of relationships).*
32. *What are causal and statistical relationships? Provide examples.*
33. *What are contingency tables? What are they used for and what do they show?*
34. *What are non-parametric criteria? Identify the advantages and disadvantages of non-parametric tests.*
35. *Main stages of selecting a non-parametric test.*
36. *Characterize non-parametric tests for independent groups (Wald–Wolfowitz test, Mann–Whitney test, Kolmogorov–Smirnov test, Kruskal–Wallis test, median test). Provide parametric analogues.*
37. *Characterize non-parametric tests for dependent groups (sign test, Wilcoxon test, Friedman chi-square test). Provide parametric analogues.*
38. *Pearson's chi-square test: calculation formula and applications. Chi-square test with Yates' correction.*
39. *Conditions and limitations of using Pearson's chi-square test. Algorithm for calculating the chi-square statistic.*
40. *Identify, characterize, and provide examples of types of relationships in statistics. What are factor and response variables?*
41. *What are correlation dependence, correlation analysis, and the correlation coefficient? Identify the main tasks of correlation analysis.*
42. *Characterize types of relationships between variables (direct and inverse causal relationships; relationships caused by one or more hidden variables; direct relationships and relationships where dependence is random).*
43. *How can a scatter plot be characterized? How can the strength and direction of correlation be determined from it?*
44. *Interpretation of correlation coefficient results. Identify the properties of the correlation coefficient.*
45. *Characterize Pearson's correlation coefficient. Conditions for its application. Sample requirements for testing the hypothesis about Pearson's correlation coefficient.*
46. *Characterize rank correlation coefficients: Spearman's, Kendall's, and Goodman–Kruskal's coefficients.*
47. *What are covariance, the coefficient of determination, and the correlation ratio? Characteristics, advantages, and disadvantages of the correlation ratio.*
48. *What do simple, partial, and multiple correlation coefficients describe?*
49. *Factors affecting the value of the correlation coefficient.*
50. *Present the algorithm for determining linear correlation.*

***Program Learning Outcomes (Extended Form)***

*As a result of studying the course "Medical Statistics", students will be able to achieve the following learning outcomes:*

| ***Learning outcomes*** | | ***Alignment of learning outcomes with competencies according to the Educational Program*** | |
|---|---|---|---|
| | | ***General competencies (soft skills)*** | ***Professional (specialized) competencies*** |
| ***PLO1*** | *Ability to apply methods of medical statistics for the collection, grouping, and preprocessing of experimental and clinical biomedical data.* | ***GC1*** *– Ability for abstract thinking, analysis, and generalization of quantitative information;* ***GC3*** *– Skills in working with information – collection, systematization, analysis, and critical evaluation of data.* | ***PC1*** *– Ability to apply methods of medical statistics for the analysis of biomedical and clinical data;* ***PC3*** *– Skills in assessing randomness and regularities in medical and biological processes.* |
| ***PLO2*** | *Ability to select and correctly use statistical characteristics and measurement scales for the analysis of random variables in biomedical engineering systems.* | ***GC1*** *– Ability for abstract thinking, analysis, and generalization of quantitative information;* ***GC2*** *– Ability to apply basic mathematical and statistical methods to solve applied problems.* | ***PC1*** *– Ability to apply methods of medical statistics for the analysis of biomedical and clinical data;* ***PC3*** *– Skills in assessing randomness and regularities in medical and biological processes.* |
| ***PLO3*** | *Ability to perform statistical hypothesis testing using parametric and non-parametric criteria and to interpret the results taking into account the engineering and medical context.* | ***GC2*** *– Ability to apply basic mathematical and statistical methods to solve applied problems;* ***GC4*** *– Ability to make well-founded decisions based on quantitative analysis and statistical conclusions.* | ***PC2*** *– Ability to select and use appropriate statistical criteria for hypothesis testing in medical research;* ***PC3*** *– Skills in assessing randomness and regularities in medical and biological processes.* |
| ***PLO4*** | *Ability to investigate relationships between variables in biomedical data using correlation analysis and to formulate well-founded conclusions for solving applied engineering problems.* | ***GC1*** *– Ability for abstract thinking, analysis, and generalization of quantitative information;* ***GC4*** *– Ability to make well-founded decisions based on quantitative analysis and statistical conclusions.* | ***PC4*** *– Ability to analyze relationships between variables and interpret the results of correlation analysis in a medical context;* ***PC1*** *– Ability to apply methods of medical statistics for the analysis of biomedical and clinical data.* |