COURSE UNIT (MODULE) DESCRIPTION

Course unit (module) title	Code
Research methods and biostatistics	

Academic staff	Core academic unit(s)
Coordinating: Assoc. prof. Lina Zabulienė (MD, PhD) **Other:** Lecturers at the Institute of Biomedical Sciences and the Institute of Health Sciences	Faculty of Medicine, M. K. Čiurlionio 21/27, LT-03101, Vilnius Coordinating teacher email: lina.zabuliene@mf.vu.lt

Study cycle	Type of the course unit
Integrated	Compulsory

Mode of delivery	Semester or period when it is delivered	Language of instruction
Mixed methods (online and(or) classroom)	4th year, 8th semester	English

Requisites	
Prerequisites: No	**Co-requisites (if relevant):** No

Number of ECTS credits allocated	Student's workload (total)	Contact hours	Individual work
5	135	66	69

Purpose of the course unit
This course unit/module aims to develop the ability to understand and apply research methods in the field of healthcare, analyze key health indicators, plan and conduct biomedical research, perform biostatistical analyses of data, correctly interpret the results obtained from statistical analyses, formulate appropriate and valid conclusions, thereby enhancing the student's awareness of the importance of research and its relevance in clinical practice. Additionally, it aims to foster an analytical and critical approach and improve the student's ability to critically appraise the results of their scientific research and the scientific literature.

Learning outcomes of the course unit	Teaching and learning methods	Assessment methods
Know and be able to apply biostatistical methods commonly used in medical research. Be capable of critically analyzing and evaluating scientific literature, including its results and claims, while considering the requirements for different types of research and distinguishing between levels of scientific evidence. Be able to design a biomedical research protocol independently and as part of a team. This includes planning a biomedical study, formulating a scientific hypothesis, establishing aims and objectives, predicting outcomes, developing a research methodology,	Lectures, seminars and independent work. The "flipped classroom" method. Analysis of scientific literature. Group discussions. Learning by teaching others. Practical exercises. Feedback.	Cumulative evaluation. Assessment after each seminar. Exam.

| | designing appropriate statistical methods, independently conducting statistical analysis of data, presenting the results, and drawing scientifically valid analytical conclusions. |
| Be able to develop literature review protocols and create bibliographic lists using bibliographic software independently. |
| Be able to express ideas fluently and persuasively in oral and written forms. |
| Be able to think critically, systematically, and creatively in order to solve problems and make appropriate decisions. |

| Content | Contact hours | | | | | | | Individual work: time and assignments | |
	Lectures	Tutorials	Seminars	Workshops	Laboratory work	Internship	Contact hours, total	Individual work	Tasks for individual work
Biostatistics	**13**		**20**				**33**	**33**	
1. Purpose of biostatistics and the concepts of population and sample. Methods of sampling, including random and non-random samples. Type of variables and descriptive statistics. the Meaning of the empirical rule and the role of confidence intervals in medical studies.	3		4				7	7	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
2. Histogram and assumption of normal distribution in medical research. Understanding of hypothesis testing for one and two samples (parametric and non-parametric criteria), including p-value. Exploration of methods for testing normality.	2		4				6	6	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
3. Construction of frequency tables for one and two variables (cross-tabulation). Ability to represent factor data graphically. Knowledge of the use of the chi-square and Fisher's Exact test. Study hypothesis testing for proportions.	2		4				6	6	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
4. Understanding of hypothesis testing for three or larger samples (analysis of variance (ANOVA)). Knowledge about applicability of the criteria for multiple comparisons.	3		4				7	7	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
5. Understand the concept of statistical association. Learn about correlation coefficients for quantitative, rank, and nominal variables. Study univariate and	3		4				7	7	Preparing for the seminar: listening to the VMA lecture, searching for

multivariate linear regression. Introduction to sample size calculation. A priori sample size according to the formulation of the statistical hypothesis. Criterion post hoc power.								information, reading and analyzing scientific literature on the lecture topic.
Research methods	13		20				33	36	
6. The importance of medical research, its types, design, methods, advantages, and disadvantages. Legal regulation of biomedical research.	2						2	2	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
7. Clinical epidemiology I. Classification and critical appraisal of scientific publications in biomedicine. Application of epidemiological research methods in biomedical research. Final thesis and the essential steps in writing process.	2		2				4	4	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
8. Questionnaires, principles of their design, validity, and reliability. Pilot study - justification of the study's relevance, criteria for selection of subjects, choice of research methodology, and organization of the research process.	2		4				6	6	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
9. Clinical epidemiology II. Assessment of incidence and prevalence. Risk assessment and calculations. Cochrane Database. Variety of bibliographic applications. Compiling a reference list.	2		6				8	8	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic. Managing bibliography programmes
10. Clinical epidemiology III. Sensitivity and specificity. Prognostic values of tests. Principles of evidence-based medicine. Scientific value of the journal and the article. Systemic reviews and principles of writing.	3		4				7	7	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
11. Requirements for a biomedical research protocol. Clinical trials. Scientific communication and methods of dissemination of scientific data.	2		4				6	9	Preparing for the seminar: listening to the VMA lecture, searching for information, reading and analyzing scientific literature on the lecture topic.
Total	26		40				66	69	

Assessment strategy	Weight %	Deadline	Assessment criteria
Assessment of seminars (practical part):	**50 %**	At each seminar	Questions and practical exercises during assessment. Maximum score for the test is 10 points.

Practical assignment of Biostatistics part (5 assessments)	25 %		
Practical assignment of Research methods part (5 assessments)	25 %		
Exam:	**50 %**	According to the Studies department timetable	The exam consists of 2 written parts: biostatistics and research methods. A score for each part of the exam is given.
Theoretical assignment of Biostatistics part (assessment)	25 %		
Theoretical assignment of Research methods part (assessment)	25 %		
Final Evaluation	100 %	At the end of the course unit/module	The final grade (FG) is based on the cumulative score system and is calculated as the arithmetic mean of the grades of Biostatistics and Research Methods parts: $FG = 0.25xBS\_T + 0.25xBS\_E + 0.25xRM\_T + 0.25xRM\_E$ [BS – part of biostatistics, MDM – part of research methods, T – tasks/tests during seminars; E – exam]. Both parts of biostatistics and research methods are considered successful if the cumulative score from seminar assessments and exams is 5 or higher. The cumulative score is calculated to the nearest hundredth without rounding

Author (-s)	Publishing year	Title	Issue of a periodical or volume of a publication	Publishing house or web link
		Required reading		
Working group of Faculty of Medicine, head of the goup J. Dadonienė	2019	Methodological guidelines for the preparation, defence and storage of final theses at the faculty of Medicine of Vilnius university		Available at: https://www.mf.vu.lt/images/Methodological_guidelines_for_teh_preparation_Faculty_of_Medicine_2023.pdf
Lingard L.	2018	Writing an effective literature review : Part I: Mapping the gap.	Perspect Med Educ. 2018;7(1):47-49.	Available at: https://pubmed.ncbi.nlm.nih.gov/29260402/
Lingard L.	2018	Writing an effective literature review : Part II: Citation technique.	Perspect Med Educ. 2018;7(2):133-135.	Available at: https://pubmed.ncbi.nlm.nih.gov/29500746/
Chidambaram AG, Josephson M.	2019	Clinical research study designs: The essentials.	Pediatr Investig. 2019;3(4):245-252.	Available at: https://pubmed.ncbi.nlm.nih.gov/32851330/
Roberts L.	2021	Twelve tips for UK medical students undertaking laboratory-based intercalated research projects.	MedEdPublish (2016). 2021 Sep 3;9:225.	Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10448456/
Murphy A, Bolderston A.	2021	Writing your first paper: An informal guide for medical radiation sciences professionals.	J Med Imaging Radiat Sci. 2021;52(3):456-465.	Available at: https://pubmed.ncbi.nlm.nih.gov/34281795/
Murphy A, Bolderston A.	2022	Writing your first paper Part 2: Submission, review, and post-publication	. J Med Imaging Radiat Sci. 2022;53(3):478-486.	Available at: https://pubmed.ncbi.nlm.nih.gov/35717378/
Subbiah V.	2023	The next generation of evidence-based medicine.	Nat Med. 2023;29(1):49-58.	Prieiga per internetą: https://pubmed.ncbi.nlm.nih.gov/36646803/

Wirth F, Cadogan CA, Fialová D, Hazen A, Lutters M, Paudyal V, Weidmann AE, Okuyan B, Henman MC.	2024	Writing a manuscript for publication in a peer-reviewed scientific journal: Guidance from the European Society of Clinical Pharmacy	Int J Clin Pharm. 2024 Feb 8.	Prieiga per internetą: https://pubmed.ncbi.nlm.nih.gov/38332208/
Mangiafico, S.S.	revised 2023	An R Companion for the Handbook of Biological Statistics.	version 1.3.9	Prieiga per internetą: https://rcompanion.org/rcompanion/
Peacock, Janet L., and Phil J. Peacock.	2020	Oxford Handbook of Medical Statistics,	Oxford University Press, Incorporated 2020	Prieiga per internetą: ProQuest Ebook Central, https://ebookcentral.proquest.com/lib/viluniv-ebooks/detail.action?docID=6230109
J. Ball, V. Bewick, L. Cheek.	2001-2005	Medical statistics.	Critical Care	Prieiga per internetą: https://www.biomedcentral.com/collections/CC-Medical
Lietuvos Respublikos Seimas	2000, red. 2023 m.	Lietuvos Respublikos biomedicininių tyrimų etikos įstatymas	Valstybės žinios, 2000-05-31, Nr. 44-1247 suvestinė red. 2023 09 01	Prieiga per internetą: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.101629/asr
Karp N.A.	2010	R Commander: an Introduction		Available at: http://cran.r-project.org/doc/contrib/Karp-Rcommander-intro.pdf
Open Access Software Environment R		R Project		Available at: https://cran.r-project.org/
Recommended reading				
White SE. eds.	2020	Basic & Clinical Biostatistics, 5e.		McGraw Hill. Available at: Basic & Clinical Biostatistics, 5e	AccessMedicine	McGraw Hill Medical (mhmedical.com)
Harris JD, Quatman CE, Manring MM, Siston RA, Flanigan DC.	2014	How to write a systematic review.	Am J Sports Med. 2014;42(11):2761–8.	Available at: https://pubmed.ncbi.nlm.nih.gov/23925575/
Pati D, Lorusso LN.	2018	How to Write a Systematic Review of the Literature.	HERD. 2018;11(1):15-30.	Available at: https://pubmed.ncbi.nlm.nih.gov/29283007/
Iskander JK, Wolicki SB, Leeb RT, Siegel PZ.	2018	Successful Scientific Writing and Publishing: A Step-by-Step Approach.	Prev Chronic Dis. 2018;15:E79.	Prieiga per internetą: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6016396/
Page MJ, et al	2021	The PRISMA 2020 statement: an updated guideline for reporting systematic reviews.	BMJ. 2021;372:n71.	Available at: https://pubmed.ncbi.nlm.nih.gov/33782057/
da Costa BR, Jüni P.	2014	Systematic reviews and meta-analyses of randomized trials: principles and pitfalls.	Eur Heart J. 2014;35(47):3336–45.	Available at: https://pubmed.ncbi.nlm.nih.gov/25416325/
Bowers D.	2019	Medical statistics from scratch – an introduction for Health Care Professionals	4th Edition	Wiley

Roberts L.	2021	Twelve tips for UK medical students undertaking laboratory-based intercalated research projects.	MedEdPublish (2016). 2021 Sep 3;9:225.	Prieiga per internetą: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10448456/
Phillips V, Barker E.	2021	Writing for publication: Structure, form, content, and journal selection.	J Perioper Pract. 2021;31(6):230-233.	Prieiga per internetą: https://pubmed.ncbi.nlm.nih.gov/34057856/
Wirth F, Cadogan CA, Fialová D, Hazen A, Lutters M, Paudyal V, Weidmann AE, Okuyan B, Henman MC.	2024	Writing a manuscript for publication in a peer-reviewed scientific journal: Guidance from the European Society of Clinical Pharmacy	Int J Clin Pharm. 2024 Feb 8.	Prieiga per internetą: https://pubmed.ncbi.nlm.nih.gov/38332208/
Malay DS.	2024	Effective Manuscript Preparation and Submission. Clin	Podiatr Med Surg. 2024;41(2):351-358.	Prieiga per internetą: https://pubmed.ncbi.nlm.nih.gov/38388131/