



Univerza v Mariboru

Medicinska fakulteta

**UČNI NAČRT PREDMETA / COURSE SYLLABUS**

<b>Predmet:</b>	<b>Raziskovanje v medicini z biostatistiko</b>
<b>Course title:</b>	<b>Research Work in Medicine with Medical Statistics</b>

Študijski program in stopnja Study programme and cycle	Študijska smer Study option	Letnik Year of study	Semester Semester
Dentalna medicina/Dental Medicine		1	2
2. stopnja/2 <sup>nd</sup> cycle			

Vrsta predmeta / Course type Obvezni/ Compulsory

Univerzitetna koda predmeta / University course code:  

Predavanja Lectures	Seminar Seminar	Vaje Tutorial	Klinične vaje Clinical training	Druge oblike študija Other forms of study	Samost. delo Individual work	ECTS
20	10	30			60	4

Nosilec predmeta / Lecturer: Prof. dr. Pavel Skok  
Doc. dr. Petra Povalej Bržan

Jeziki / Predavanja / Lectures: slovenščina/slovene  
 Languages: Vaje / Tutorial: slovenščina/slovene

Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti: Prerequisites:

   

Vsebina:	Content (Syllabus outline):
<p>Opredelevitev pojma znanosti. Razmejitve med strokovnim in raziskovalnim delom kot virom novega znanja. Spoznati splošne metode znanstveno raziskovalnega dela, pomen povezanosti teoretičnih znanj in uporabe v klinični medicini, algoritmi odločanja. Raziskovalno delo kot metoda preverjanja kliničnih odločitev in odgovornega sledenja posledic. Etnična in pravna vprašanja pri raziskovanju v biomedicini. Definiranje odnosov vzrok – posledica v biomedicini in vloga presejalnih testov. Razumevanje osnovnih statističnih pojmov v biomedicini (incidenca, prevalenca, pozitivna in negativna napovedna vrednost, občutljivost in specifičnost testov, lažno pozitivnih in negativnih rezultatov), pomena relativnega tveganja in razmerja obojev. Razlikovanje prospektivnih, retrospektivnih, epidemioloških, kontroliranih, randomiziranih, kohortnih, primer – kontrola in dvojno slepih vrst raziskav. Pomen računalniške tehnologije in statističnih orodij pri znanstveno raziskovalnem delu. Statistični del: raziskovalni proces, kvalitativna in kvantitativna analiza podatkov, osnovni statistični pojmi (vrste spremenljivk, verjetnostne porazdelitve, mere</p>	<p>Definition of the term science. Boundaries between scientific and research work as sources of new knowledge. Common methods of scientific research, meaning of liaison of theoretical knowledge and its application in clinical medicine, algorithms of decision making. Research work as method of clinical decisions and responsible consequences following-up testing. Ethical and legislative questions in biomedicine research. Definition of relationship cause – consequence in biomedicine and role of screening tests. Comprehension of basic statistical terms in biomedicine (incidence, prevalence, positive and negative prognostic values, sensitivity and specificity of tests, false positive and negative results), meaning of relative risk and expectation ratio. Distinguishes between prospective, retrospective, epidemiologic, followed-up, randomised, cohort, case – control, and double blind researches. Importance of computer technology and statistical software in scientific research work. Statistical part: the research process, qualitative and quantitative data analysis, basic statistical concepts (types of variables, probability distributions, central tendency</p>

centralne tendence in mere variabilnosti), osnove statističnega sklepanja (frekvenčna porazdelitev, ničelna domneva, standardna napaka, interval zaupanja), univariatna statistična analiza (predstavitev podatkov: tabelarna, grafična), univariatni statistični testi, bivariatna statistična analiza (odvisnosti med spremenljivkama), bivariatni parametrični testi (t-test, korelacija, ANOVA, t- test za odvisne vzorce), bivariatni neparametrični statistični testi. (Mann-Whitney U test, neparametrična korelacija, hi-kvadrat test, Kruskal-Wallis H test, Median test, neparametrični statistični testi za odvisne vzorce).

Osnove genetike, anatomije in fiziologije laboratorijskih živali. Primerjava laboratorijskih živali in človeka, prednosti in slabosti živalskih modelov. Etika pri delu z laboratorijskimi živalmi. Osnove zakonodaje na področju laboratorijskega dela in dela z laboratorijskimi živalmi.

Celični in tkivni modeli v predkliničnem raziskovanju.

Genetsko spremenjeni organizmi in njihova vloga v predkliničnih raziskavah.

Elektro- in opto-fiziološke metode. Obdelava in statistična analiza podatkov pri predkliničnem raziskovanju. Pregled literature in dostop do znanstvene literature. Publciranje v predkliniki. Pregled sodobnih laboratorijskih metod. Seminarske vaje: metode statistične genetike za iskanje povezav genotip/fenotip.

and measures of variability), basics of statistical conclusions (frequency distribution, null hypothesis, standard error, confidence interval), univariate statistical analysis (presentation of data: tables, graphs), single variant statistical tests, bivariate statistical analysis (dependence between variables), bivariate parametric tests (t - test, correlation, ANOVA, t-test for paired samples), bivariate nonparametric statistical tests (Mann - Whitney U test, non-parametric correlation, chi-square test, Kruskal - Wallis H test and the median test, nonparametric statistical tests for dependent samples).

Basic genetics, anatomy and physiology of laboratory animals. Comparison between laboratory animals and humans, advantages and disadvantages of animal models. Animal research ethics. Legislation in the field of laboratory work and work with laboratory animals. Cellular and tissue models in basic medical research. Genetically modified organisms and their role in basic medical research. Electrical and optical methods in basic medical research. Statistical analysis of data in basic medical research. Literature review and access to scientific literature. Publishing in basic medical research. Review of modern laboratory methods. Seminars work: methods of statistical genetics for the search for genotype / phenotype.

#### Temeljni literatura in viri / Readings:

##### Temeljni viri:

1. Norman K. Denzin (Editor), Yvonna S. Lincoln (Editor) Handbook of Qualitative Research, 2nd ed. Sage publications, London 2000.
2. Field A. Discovering statistics using SPSS. 3rd ed. SAGE Publications, 2009.

##### Dopolnilni viri:

1. Beauchamp TL, Childress JE. Principles of biomedical ethics, 5th ed. Oxford University Press, Oxford 2001.
2. Fox. J.G.: The mouse in biomedical research. Second edition. Volume I & II. Academic Press, 2006.
3. Pawley J. Handbook of Biological Confocal Microscopy. 3rd ed. Springer, 2006.
4. Zakon o zaščiti živali (ZZZiv-UPB3), Uradni list RS, št. 38/2013 z dne 3. 5. 2013.
5. Pravilnik o pogojih za izvajanje poskusov na živalih. Uradni list RS, št 37/2013, 29. 4. 2013.
6. Robert Nussbaum, Roderick McInnes, Huntington Willard. Thompson & Thompson Genetics in Medicine. 8th ed., Philadelphia: Elsevier, 2015

#### Cilji in kompetence:

Poglaviti cilj predmeta je pridobitev nekaterih teoretičnih znanj in praktičnih veščin, ki jih potrebuje raziskovalec pri raziskovalnem delu v biomedicini. Spoznati osnove raziskovalnega dela v biomedicini in bioznanostih, povezavo in pomen epidemiologije, biostatistike in njenih orodij (statističnih testov, vrednotenja), vloga izsledkov na odločanje. Študenti bodo znali na osnovi pregleda znanstvene literature ugotoviti trenutno stanje znanja na področju določene biomedicinske problematike, odkriti še neodgovorjena relevantna znanstvena vprašanja, postaviti hipotezo in načrtovati biomedicinsko študijo, ki bo ustrezno ovrednotila hipotezo. Študenti bodo

#### Objectives and competences:

The major aim of the course is to gain the theoretical knowledge and practical skills needed for a researcher in biomedical research. Acquiring of basic knowledge about researching in biomedicine and biosciences, relationship and importance of epidemiology, biostatistics and their tools (statistic tests, evaluation) importance of findings for decision making. Students will be able to perform systematic review of scientific literature and to establish the state-of-art in the specific biomedical research topic. Students will be able to identify relevant open scientific questions, to set the appropriate hypothesis and to design biomedical study to evaluate the hypothesis. Students will be able to write and

<p>sposobni napisati in izvesti raziskovalni projekt s katerim bodo odgovorili na določena klinična vprašanja s pomočjo rezultatov biokemijskih in genetskih laboratorijskih preiskav.</p> <p>Študenti bodo poznali in razumeli delovanje najpomembnejših tehnologij za raziskovanje na področju biomedicine, predvsem biokemije in genetike, in bodo znali uporabiti tehnologije za reševanje relevantnih kliničnih vprašanj.</p>	<p>execute the research project to answer specific clinical questions using the results from biochemical and genetic laboratory investigations.</p> <p>Students will understand the working the state-of-art laboratory technology most relevant for biomedical research, including biochemistry and genetics, and will be able to use the technology to adress relevant clinical issues.</p>
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**Predvideni študijski rezultati:****Intended learning outcomes:**

<p>Znanje in razumevanje: pomena znanosti, kritičnega vrednotenja izsledkov raziskav v biomedicini in preverjanje domnev. Sposobnost analize znanstveno raziskovalnih prispevkov, vsebinska in kvalitativna.</p> <p>Prenosljive/ključne spretnosti in drugi atributi: načrtovanje raziskave, pomen natančnosti in točnosti pri zbiranju podatkov in izvajanju raziskave, obdelava in kvantitativna/kvalitativna interpretacija pridobljenih rezultatov v skladu z znanimi dejstvi in pridobljenimi novimi spoznanji.</p>	<p>Knowledge and understanding: knowledge and understanding of science, critical assessment of the research results in biomedicine and hypothesis testing. Ability of scientific research contributions, content and quality analyse.</p> <p>Transferable/key skills and other attributes: research planning, meaning of precision and accuracy in data collection, carrying out of the research, data processing, quantitative and qualitative interpretation of results according to known facts and new findings.</p>
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**Metode poučevanja in učenja:****Learning and teaching methods:**

<p>Predavanja (interaktivna) Seminar Vaje (seminarske 10 , praktične 20)</p>	<p>Lectures (interactive) Seminars Tutorial (seminar 10, practical 20)</p>
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**Delež (v %) /****Weight (in %) /****Assessment:**

<b>Načini ocenjevanja:</b>	<b>Delež (v %) / Weight (in %) /</b>	<b>Assessment:</b>
<p>Način (izpit, ustno izpraševanje, naloge, projekt) <b>ŠTUDIJSKE OBVEZNOSTI ŠTUDENTOV</b> Glede na sklep Senata z dne 13. 6. 2011 je za študente obvezna 50 % udeležba na predavanjih.</p> <p>POGOJI ZA PRISTOP K POSAMEZNEMU PREVERJANJU ZNANJA: opravljen seminar in vaje.</p> <p><b>Računalniški izpit</b></p>	<b>100 %</b>	<p>Type (examination, oral, coursework, project): <b>ACADEMIC OBLIGATIONS OF STUDENTS</b> According to the decision of the Senate on June 13, 2011, 50% attendance at lectures is obligatory for students.</p> <p><b>REQUIREMENTS FOR ACCESS TO INDIVIDUAL KNOWLEDGE CHECKING:</b> completed seminar assignment and exercises</p> <p><b>Computer exam</b></p>

**Reference nosilcev / Lecturer's references: PAVEL SKOK**

- Pintar Š, Rupnik M, SKOK P. Clostridium difficile isolation and characterisation: results of a pilot study. United European Gastroenterology journal, ISSN 2050-6414. 2018, vol. 6, iss. 8, suppl., str. A291-A292.
- Čeranić D, SKOK P, Zorman M. Are interleukins useful in predicting the severity of acute pancreatitis?. Gastroenterology, ISSN 1528-0012. [Online ed.], 2017, vol. 152, issue 5, suppl. 1, str. S-279.
- Repnik K, Koder S, SKOK P, Ferkolj I, Potočnik U. Transferrin level before treatment and genetic polymorphism in HFE gene as predictive markers for response to adalimumab in Crohn's disease patients. Biochemical genetics, 2016, str. [1-11].
- Zupančič K, Skok K, Repnik K, Weersma RK, Potočnik U, SKOK P. Multi-locus genetic risk score predicts risk for Crohn's disease in Slovenian population. World journal of gastroenterology 2016, vol.22,issue 14, str. 3777-3784.

5. Koder S, Repnik K, Ferkolj I, Pernat Drobež C, SKOK P, Weersma RK, Potočnik U. Genetic polymorphism in ATG16L1 gene influences the response to adalimumab in Crohn's disease patients. *Pharmacogenomics*, 2015, vol. 16, no. 3, str. 191-204.
6. Gorenjak M, Gradišnik L, Trapečar M, Pistello M, Pinto Kozmus C, Škorjanc D, SKOK P, Langerholc T, Cencič A. Improvement of lipid profile by probiotic/protective cultures: study in a non-carcinogenic small intestinal cell model. *The New microbiologica*, 2014, vol. 37, no. 1, str. 51-64.

**Reference nosilca / Lecturer's references: PETRA POVALEJ BRŽAN**

1. POVALEJ P, Lenič M, Zorman M, Kokol P, Dinevski D. Accuracy of intelligent medical systems. *Computer methods and programs in biomedicine*, ISSN 0169-2607. , 2005, vol. 80, suppl. 1, str. S95-S105.
2. POVALEJ P, Verlič M, Štiglic G. Discovery systems. V: MEYERS, Robert A. (ur.). *Encyclopedia of complexity and systems science*. New York: Springer, 2009, vol. 2, str. 1982-2002, ilustr.
3. Fijačko N, POVALEJ P, Štiglic G. Mobile applications for type 2 diabetes risk estimation : a systematic review. *Journal of medical systems*, ISSN 1573-689X, oct. 2015, vol. 39, iss. 10, 10 str. <http://link.springer.com/article/10.1007/s10916-015-0319-y/fulltext.html>, doi:10.1007/s10916-015-0319-y.
4. Štiglic G, POVALEJ P, Fijačko N, Wang F, Kalousis A, Delibašić B, Obradović Z. Comprehensible predictive modeling using regularized logistic regression and comorbidity based features. *PloS one*, ISSN 1932-6203, 2015, vol. 10, no. 12, str. 1-6, ilustr. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0144439>, doi: 10.1371/journal.pone.0144439.
5. POVALEJ P, Gallego JA, Farina D, Holobar A. On repeatability of motor unit characterization in pathological tremor. V: *International Conference on Neurorehabilitation, ICNR 2012, Toledo, Spain, November 14-16, 2012*. PONS, José L. (ur.), TORRICELLI, Diego (ur.), PAJARO, Marta (ur.). *Converging clinical and engineering research on neurorehabilitation*, (Biosystems & Biorobotics, ISSN 2195-3562). Heidelberg [etc.]: Springer, cop. 2013, part 1, str. 553-556.
6. Dinevski D, POVALEJ P, Kravos M. Intelligent data analysis for the diagnosis of alcohol dependence syndrome. *Journal of international medical research*, ISSN 0300-0605, 2011, vol. 39, no. 3, str. 988-1000.