

DESCRIPTION OF COURSE UNIT FOR DOCTORAL STUDIES AT VILNIUS UNIVERSITY

Scientific Area/eas, Field/ds of Science	Medical and Health Sciences (M 000): Medicine (M 001); Dentistry (M 002); Public Health (M 004); Natural Sciences (N 000): Biology (N 010).			
Faculty, Institute, Department/Clinic	Faculty of Medicine, Institute of Translational Health Research			
Course unit title (ECTS credits, hours)	Translational medicine 8 credits (217 hours)			
Study method	Lectures	Seminars	Consultations	Self-study
Number of ECTS credits	1.5	2.1	-	4.4
Method of the assessment (in 10 point system)	<u>Prepare and present a report</u> on the applicability perspective of the PhD research topic (including the implied strategy for the specific study), its novelty, and impact, taking into account the existing literature. <u>Evaluation Criteria for the Presentation:</u> • Overall structure and scope of the presentation, clarity in presenting knowledge, argumentation, conciseness, and specificity (2 points); • Summary, formulation of key issues, presentation and justification of conclusions (2 points); • Application of reviewed knowledge to the PhD dissertation work (4 points); • Organization of visual aids, ability to participate in the discussion, handling questions, oratory skills (2 points). Minimum passing score – 5.			
PURPOSE OF THE COURSE UNIT				
To develop PhD students' ability to effectively plan and carry out translational health research – from improving skills in research funding and project management to implementing studies and applying results in practice – with the goal of increasing the impact of research on individual and public health. Doctoral students will gain knowledge about the use of modern technologies, the development of new diagnostic methods and treatments, and the planning of clinical studies. In addition, they will acquire knowledge and strengthen their skills in areas such as digital medicine, personalized medicine, gene therapy, and biotechnology.				
THE MAIN TOPICS OF COURSE UNIT				
1. Introduction to Translational Medicine. Medicine and biological evolution. Global health challenges. The role of personalized medicine in healthcare systems. Health policy development, economic analysis of care systems, and innovation assessment. The culture of collaboration and the benefits of open access. 2. Preclinical Research. Evaluation of drug safety, pharmacokinetics, and efficacy. Toxicology studies, determination of maximum dosage, efficacy trials. Workflow and requirements for working with laboratory animals. The clinical trial cycle: Phases I, II, III, and IV. 3. Personalization and Integration of Patient Data into Treatment Strategies. Biobanks and clinical data: linking and analysis of datasets. 4. Gene Editing. Mechanisms of gene editing. Application opportunities and challenges (off-target effects, efficiency limitations, etc.). Ex vivo and in vivo gene				

editing: differences and applications. Animal and cell models. Use of gene editing in biomarker discovery and development of targeted therapies. Gene editing in tissue engineering and regenerative medicine. Germline gene editing: ethical and legal considerations. Gene therapy and individualized treatment.

5. Development of Immunotherapy. Discovery of new immune system targets and their clinical relevance. Biomarkers to predict immunotherapy response. Engineering of immune cells. Nanoparticles in immunotherapy: delivery of immunostimulants. Oncolytic viruses as immunotherapy tools. Managing long-term immune response and reducing side effects. The role of neoantigens in personalized immunotherapy. Cancer vaccines: from prevention to therapeutic use.

6. Development and Biological Accuracy of Organoids. Application in drug testing and toxicity evaluation. Organoids as disease models: oncology, neurodegenerative and infectious diseases. Personalized medicine using patient-derived organoid models. 3D bioprinting of organoids. Genetic modification of organoids for research. Immunological studies with organoids: integration with the immune system. Studies on organoid-microbiome interactions. Ethical challenges and regulatory issues in the use of organoids.

7. Foundations of Digital Medicine. Concept and evolution of digital medicine. The role of big data in healthcare. Genetic data and its role in medicine. Use of genetic information in diagnosis and treatment. Clinical biomarkers and their role in decision-making. Pharmacogenomics and individualized treatment. Security and privacy of genomic data.

8. Application of Biotechnology and Nanotechnology. Nanomedicine and targeted therapy strategies: drug delivery, gene therapy, nanosensors for diagnostics, regenerative medicine, nanotechnology in antimicrobial therapy. Use of artificial intelligence and machine learning in healthcare. AI in evaluating drug efficacy, personalizing treatment, and optimizing study design. Model training and validation. Ethical and regulatory challenges in digital medicine. Data privacy and security in health technologies. Predictive health analytics models.

9. Science Funding Instruments, Proposal Writing, and Budget Planning
Collaboration between science and business. Entrepreneurship. Patenting.

10. Scientific Publishing. Scientific journals and their evaluation metrics. Preparing a scientific article and its typical structure. Communication with reviewers. Peer review of scientific publications.

RECOMMENDED LITERATURE SOURCES

1. Principles of Translational Science in Medicine: From Bench to Bedside, red. Martin Wehling, 2021.
2. Clinical and Translational Science: Principles of Human Research. ISBN: 9780128021019 (VU DB: ClinicalKey)
3. Essential Concepts in Clinical Research. Kenneth Schulz & David A. Grimes, 2019, Elsevier ISBN: 9780702073946 (VU DB: ClinicalKey)
4. The Philosophy of Evidence-Based Medicine. Jeremy Howick, 2011, ISBN: 9781444342659 (VU DB: ProQuest)
5. Painless Evidence-Based Medicine. Antonio L. Dans, Leonila F. Dans, Maria Asuncion A. Silvestre. 2017, Wiley-Blackwell. ISBN: 9781119196266 (VU DB: ProQuest)
6. Academic Entrepreneurship: How to Bring Your Scientific Discovery to a Successful Commercial Product, red. Jeffrey A. Robinson ir Vincent L. S. Wang, 2020.
7. Clinical Trials: A Methodologic Perspective (Wiley Series in Probability and Statistics) 3rd Edition. Steven Piantadosi, 2017.
8. Nanomedicine. Technologies and Applications. 2nd Edition - March 14, 2023. Editor: Thomas J Webster, Barrett JE, Coyle JT, Williams M, eds.

9. Organoid Technology for Disease Modelling and Personalized Treatment. Badrul Hisham Yahaya, 2022.
10. Organoids Stem Cells, Structure, and Function. Kursad Turksen, 2019.
11. Translational Neuroscience: Applications in Psychiatry, Neurology, and Neurodevelopmental Disorders. Cambridge University Press; 2012.
12. Big Data in Healthcare: Statistical Analysis and Predictive Modeling, Farrokh Alemi, 2019.
13. Journal of Science Translational medicine
<https://www.science.org/journal/stm>

CONSULTING LECTURERS

1. Coordinating lecturer: Laura Pranckėnienė (Dr.)
2. Dominyka Dapkutė-Sadauskienė (Dr.)
3. Karolis Ažukaitis (Assoc. Prof., Dr.)
4. Tomas Poškus (Prof., Dr.)

APPROVED:

By Council of Doctoral School of Medicine and Health Sciences at Vilnius University:
4th of June 2025

Chairperson of the Board: Prof. dr. Janina Tutkuvienė