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**COURSE UNIT DESCRIPTION**

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| **Course unit title** | **Code** |
| **Clinical pharmacology, drug approval and safety** | **VRVS3115** |

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| **Lecturer(s)** | **Department(s)** |
| **Coordinating:** Prof. Jolanta Gulbinovič  **Others: assist.** Dr. Ingrida Lisauskienė  assist. Dr. Tomas Janušonis | Department of Pathology, Forensic medicine and Pharmacology. Čiurlionio 21, Vilnius |

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| **Cycle** | **Level of the course unit** | **Type of the course unit** |
| cycle (integrated studies) |  | Compulsory |

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| **Mode of delivery** | **Period of delivery** | **Language of instruction** |
| Lectures, seminars, practical work | 11 semester | Lithuanian, English |

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| **Prerequisites and corequisites** | |
| **Prerequisites:** A student must have completed the following courses: anatomy, biochemistry, physiology, pharmacology, microbiology, pathology and internal medicine**.** | **Corequisites (if any):** None |

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| **Number of ECTS credits allocated to the course unit** | **Total student’s workload** | **Contact hours** | **Self-study hours** |
| 3 | 80 | 40 | 40 |

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| **Purpose of the course unit**  **Programme competences to be developed** | | |
| To give the understanding about development and life cycle of medicines, benefit risk balance and measures to optimise it.  To familiarise with the principles of clinical pharmacology and application of them in practice; to understand the reason for variation of drug effects in different patients or patient groups, e.g., in paediatric patients, elderly, pregnancy and lactation, in patients with renal or hepatic impairment; to teach how to choose the best treatment for a particular patient, how to assess efficacy and safety of drug treatment; to introduce principles of drug interactions; to teach to recognise adverse drug reaction and to report to competent authority; to teach how critically appraise the results of clinical trials, how to interpret information about the medicines and where to search for independent information on medicines. | | |
| **Learning outcomes of the course unit** | **Teaching and learning methods** | **Assessment methods** |
| After the course the student will be able |  |  |
| * To understand and describe drug development and life cycle, benefit risk balance of medicines, aim for risk management, risk minimisation measures and effectiveness of risk minimisation. | During practical work, the students work in small groups, solve the problems and discuss clinical situations, learn how to find necessary information and how to interpret information critically.  During the course, the students have to fulfil specific task for self-study: describe adverse drug reaction and prepare the report to competent authority; to prescribe treatment for specific patients; to evaluate rationality of drug prescribing in specific given situation | The knowledge and understanding of students is checked during every practical work – short written or oral test.  Self-study work (ADR reporting, and prescription of treatment) and work in class is scored in 10 points system. This score makes up 15% of final exam score.  Self-study work evaluating rationality of treatment is scored in 10 points system. This score makes up 15% of final exam score.  After finalisation of the course – final examination. It is scored in 10 points system. This score makes up 70% of final exam score. |
| * Will be able to use in practice the principles of rational prescribing and use of medicines, to assess effectiveness and safety of drug treatment, to predict possible drug-drug interaction; to recognise and differentiate adverse drug reactions, to establish causal relationship and to report to the competent authority (State medicines Control Agency). |
| * Will be able to evaluate patient and drug interaction specificity, and make a dose or treatment adjustment for patients with renal or hepatic impairment and for elderly. Will understand therapeutic drug monitoring. |
| * Will be able to assess benefit and risk of drug treatment in pregnancy and lactation. |
| * Will be able to interpret critically the results of clinical trials, and drug information. | During practical work, the students will read given publications of clinical trials and will apprise the quality of these trials and reliability of the results; will discuss the quality indicators of clinical trials and interpretation of results. |

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| **Topics** | **Contact work hours** | | | | | | | **Time and tasks of self-study** | |
| Lectures | Consultations | Seminars | Practice | Laboratory work | Practical training | **Total contact hours** | **Self-study** | **Tasks** |
| 1. Development and life cycle of medicines, benefit risk balance and measures to optimise it | 1 |  |  | 2 |  |  | **3** | **2** | To prepare for practical work, self-assessment test |
| 2. Clinical pharmacokinetics, therapeutic drug monitoring, drug interaction | 1 |  | 2 |  |  |  | **3** | **2** | To prepare for practical work, self-assessment test |
| 3. Adverse drug reactions, seriousness, severity and causality | 1 |  |  | 4 |  |  | **5** | **4** | To prepare for practical work, self-assessment test |
| 4. Rational use of medicines. Principles of rational use of antibiotics | 1 |  | 2 | 4 |  |  | **7** | **6** | To prepare for practical work, self-assessment test |
| 5. Clinical pharmacology of drug use in patients with renal or hepatic impairment | 1 |  |  | 4 |  |  | **6** | **6** | To prepare for practical work, self-assessment test |
| 6. Clinical pharmacology of drug use in critically ill patients |  |  |  | 4 |  |  | **4** | **6** | To prepare for practical work, self-assessment test |
| 7. Paediatric and geriatric clinical pharmacology | 1 |  |  | 3 |  |  | **3** | **6** | To prepare for practical work, self-assessment test |
| 8. Drug use in pregnancy and lactation | 2 |  |  | 3 |  |  | **5** | **6** | To prepare for practical work, self-assessment test |
| 9. Evaluation of clinical trials |  |  | 4 |  |  |  | **6** | **2** | To prepare for practical work, self-assessment test |
| **Total** | **8** |  | **8** | **24** |  |  | **40** | **40** |  |

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| **Assessment strategy** | **Weight (%)** | **Assessment period** | **Assessment criteria** |
| Self-study and preparations for classes | - | During the course | Preparing for the class students have to solve self-assessment test. Solution of tests is obligatory; however, they are not graded. The objective of tests is self-assessment. |
| Presentation of the project at the end of course | 100 | After the course | Every group receives a problem/situation at the beginning of the course. The problem should be solved and presented as a group work. Duration of the presentation 20 min.  Evaluation criteria:   1. Defining the problem, solution plan (2 points) 2. Search and choice of literature or other material (2 points) 3. Structure of presentation, presentation of information/knowledge, argumentation, discussion (2 points) 4. Summary, conclusions/solutions (2 points) 5. Ability to discuss, respond to questions (2 points)   Maximal grade – 10 points, minimal acceptable grade – 5 points.  Impact of every student is defined by the group.  Example: the project gets 8 points. The student with the impact of 100% gets 8 points, the student with the impact 0f 60% gets 5 points. |

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| **Author** | **Year of publication** | **Title** | **No of periodical**  **or vol. of publication** | **Publication place and publisher**  **or Internet link** |
| **Reading list** | | | | |
| McKay GA, Walters MR, Ritchie ND | 2021 | Clinical pharmacology & therapeutics. Lecture notes | 10 ed. | Wiley Blackwell |
| Reid JL, Rubin PC, Walters MR | 2013 | Lecture notes: Clinical pharmacology & therapeutics | 9 ed. | Blacwell publishing |
| **Additional literature** | | | | |
| Websites: [www.vvkt.lt](http://www.vvkt.lt); [www.emea.eu](http://www.emea.eu) | | | | |
| Greenhalgh T. | 2019 | How to read a paper: the basics of evidence-based medicine and healthcare | 6 ed. | Wiley Blackwell |