

| | | | |
|--|-----------------|--|---------------|
| Study program: Integrated academic studies of Pharmacy | | | |
| Type and level of the study program: integrated academic studies | | | |
| Course title: CLINICAL DRUG TRIALS (PhV-TRIAL) | | | |
| Teacher: Jelena M. Cvejić Hogervorst, Momir M. Mikov, Aleksandar L. Rašković, Aleksandra D. Nikolić, Svetlana S. Goločorbin Kon, Milica T. Atanacković Krstonošić, Mira P. Mikulić | | | |
| Course status: elective | | | |
| ECTS Credits: 3 | | | |
| Condition: Special pharmacology I, II | | | |
| Course aim The main objectives of the subject are to introduce students to the procedures, regulations and protocols necessary for clinical trials prior to release to the market, as well as pointing out the importance of clinical trials. Also, it is necessary to acquire knowledge in the field of legislation relating to the clinical trials and registration of the tested drug. Acquisition of theoretical foundations that enables the student to analyze specific examples and accept principles and procedures of clinical tests. | | | |
| Expected outcome of the course: Knowledge about the essence of clinical tests and their significance for the registration of safe and effective drug. Procedures and course of clinical trials. Types of tests - clinical trials phases, basic documentation. | | | |
| Course description <i>Theoretical education</i> 1. Clinical trials - introduction, purpose. 2. Basic concepts and definitions. 3. Phases of clinical trials. 4. International regulatory requirements. 5. Quality assurance. <i>Practical education: exercises, other forms of education, research related activities</i> 1. Analysis of clinical studies. Documentation. | | | |
| Literature <i>Compulsory</i> 1. ICH guidelines – Guideline for Good Clinical Practice, 1996. [Online] Available from: www.ich.org <i>Additional</i> 2. Friedman LM, Furberg CD, DeMets DL. Fundamentals of Clinical Trials 4 th Ed. Springer; 2010. 3. Hackshaw A. A Concise Guide to Clinical Trials. A John Wiley & Sons; 2009. | | | |
| Number of active classes | | | Other: |
| Lectures: 30 | Practice: 15 | Other types of teaching: Research related activities: | |
| Teaching methods Lectures. Theoretical exercises. | | | |
| Student activity assessment (maximally 100 points) | | | |
| Pre-exam activities | points | Final exam | points |
| Lectures | 10 | Written | 70 |
| Practices | 20 | Oral | |
| Colloquium | | | |
| Essay | | | |