



Study program: Integrated Academic Studies in Pharmacy			
Course title: Clinical Drug Trials			
Teacher: Jelena M. Cvejić, 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> <ol style="list-style-type: none"> 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</i> <ol style="list-style-type: none"> 1. Analysis of clinical studies - examples. Documentation. 			
Literature <i>Compulsory</i> <ol style="list-style-type: none"> 1. ICH Efficacy Guidelines, E6 Good Clinical Practice. 2016. [Online] Available from: www.ich.org <i>Additional</i> <ol style="list-style-type: none"> 1. Friedman LM, Furberg CD, DeMets DL. Fundamentals of Clinical Trials. 4th ed. Springer; 2010. 2. Hackshaw A. A Concise Guide to Clinical Trials. A John Wiley & Sons; 2009. 			
Number of active classes	Theoretical classes: 30	Practical classes: 15	
Teaching methods Lectures. Theoretical exercises.			
Student activity assessment (maximally 100 points)			
Pre-exam activities	points	Final exam	points
Lectures	20	Written	20
Practices		Oral	20
Colloquium		
Essay	40		