

<i>Name of the course</i>	Elective course: Understanding clinical trials		Code	
<i>Type of study program Cycle</i>	Integrated university study, medicine		Year of study	3
<i>Credits (ECTS) :</i>	1	<i>Semester</i>	Number of hours per semester (1+e+s)	0l+15s+19e
<i>Status of the course:</i>	elective	<i>Preconditions:</i>	<i>Comparative conditions:</i>	/
<i>Access to course:</i>	Third year students		<i>Hours of instructions:</i>	According to schedule
<i>Course teacher:</i>	Prof. Ana Maruši. MD, PhD			
<i>Consultations:</i>	As agreed with students			
<i>E-mail address and phone number:</i>	ana.marusic@mefst.hr , +385 98 508 647			
<i>Associate teachers</i>	Nensi Čaćić, MD Jakov Matas, MD			
<i>Consultations:</i>	As agreed with students			
<i>E-mail address and phone number:</i>	nensi.cacic@mefst.hr jakov.matas@mefst.hr			
<i>The aims of the course:</i>	The aims of the course are: To enable students with skills and knowledge necessary for understanding clinical trials			
<i>Learning outcomes (general and specific competences):</i>	<p><u>General outcomes</u></p> <p><input type="checkbox"/> To describe the importance of clinical trials</p> <p><input type="checkbox"/> To describe the basic principles of good clinical practice</p> <p><u>Specific outcomes</u></p> <p><input type="checkbox"/> To interpret intention-to-treat and per-protocol analysis</p> <p><input type="checkbox"/> To identify most important outcomes of clinical trials</p> <p><input type="checkbox"/> To list and provide examples of different clinical trial designs</p> <p><input type="checkbox"/> To recognize the importance of randomization and blinding</p>			
<i>Course content (Syllabus):</i>	<p>Each day will start with 3 hours of seminars, followed by 2 hours of practical.</p> <p>Day 1 Seminar: Types of Trial Designs Practical: Registering clinical trials</p> <p>Day 2 Seminar: Randomization and Masking Practical: Good Clinical practice</p> <p>Day 3 Seminar: Outcomes and Analysis Practical: Journal club</p> <p>Day 4 Seminar: Reporting results Practical: CONSORT statement</p>			

	Day 5 Seminar: Beyond clinical trials Practical: Choosing evidence for clinical practice			
Format of instruction (mark in bold)	Lectures	Exercises	Seminars	Independent assignments
	Consultations	Work with mentor	Field work	Other
Student responsibilities	Presence at teaching activities: 80% seminars, 100% practicals.			
Screening student work (mark in bold)	Class attendance	Class participations	Seminar essay	Practical training
	Oral exam	Written exam	Continuous assessment	Essay
Detailed evaluation within a <i>European system of points</i>				
STUDENTS RESPONSIBILITIES	HOURS	PROPORTIONS OF ECTS CREDITS	PROPORTIONS OF GRADE	
Class attendance and participations	25	0.3	20%	
Seminar essay	10	0.3		
Written exam	50	0.4	80%	
Oral exam	-			
Total	85	1	100	
Further clarification:				
<p>Final score: The final assessment is carried out according to the Regulation of Studies of the University of Mostar and applies to all study groups. According to the Regulations on studying final grade is obtained as follows: A = 91-100% 5 B = 79 to 90% 4 C = 67 to 78% 3 D = 55 to 66% 2 F = 0 to 54% 1</p>				
Required literature:	Marušić M, editor. Principles of Research in Medicine. 2nd ed. Zagreb: Medicinska naklada; 2015.			
Optional literature:	Guyatt G, Rennie D, Meade MO, Cook DJ. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. 3. ed. McGraw-Hill Education; 2014. Livingston EH, Lewis RJ. JAMA Guide to Statistics and Methods. 1. ed. McGraw-Hill Education; 2020. Course materials, available in SUMARUM.			

<i>Additional information about the course</i>	
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Annexes: calendar classes

<i>The number of teaching units</i>	TOPICS AND LITERATURE
<i>I.</i>	Title: What is a clinical trial?
	Short description: Understanding study designs, registration of clinical trials, transparency
	Literature: Required literature, course materials in SUMARUM
<i>II.</i>	Title: Good Clinical Practice
	Short description: Definition and content of good clinical practice, methodological approaches to clinical trials.
	Literature: Required literature, course materials in SUMARUM
<i>III.</i>	Title: What is the result of a clinical trial?
	Short description: Outcomes and analysis of trial data, critical analysis of published reports on clinical trials
	Literature: Required literature, course materials in SUMARUM
<i>IV.</i>	Title: Reporting clinical trials
	Short description: Reporting guidelines for clinical trials, CONSORT checklist
	Literature: Required literature, course materials in SUMARUM
<i>V.</i>	Title: Beyond clinical trials
	Short description: Translation to practice, metaanalysis, clinical practice guidelines
	Literature: Required literature, course materials in SUMARUM