

Study programme	MEDICAL STUDIES IN ENGLISH						
Cycle	INTEGRATED		Type	UNIVERSITY			
Study track	-		Module	-			
Year of study	3		Semester	2			
Course title	UNDERSTANDING CLINICAL TRIALS		Course code	MFMSEI05			
ECTS	1.5		Status	ELECTIVE			
Teaching hours 25			Lectures	Exercises	Seminars	Practice	
			0	10	15	-	
Teachers	Prof. Ana Marušić, MD; PhD				1		
	Nensi Bralkić, DMD; PhD			2	6		
	Miro Vuković, MD			8	8		
Course objectives	The objective of the course is to strengthen student's knowledge about clinical trial and critical thinking about evidence for health interventions						
Course learning outcomes	Learning outcome (LO) Student:				Course learning outcome code	LO code at the study program level	
	To describe the importance and structure of a clinical trial				IU-MFMSEI05-1	IU-MSE7	
	To describe basic principles of good clinical practice				IU-MFMSEI05-2	IU-MSE12	
	To interpret intention-to-treat and per-protocol analysis				IU-MFMSEI05-3	IU-MSE12	
	To identify different clinical trial designs				IU-MFMSEI05-4	IU-MSE7	
	To understand the principles of randomization, blinding and bias				IU-MFMSEI05-5	IU-MSE7	
Prerequisites for the course enrolment	In accordance with the Rulebook on the Integrated Studies at the School of Medicine University of Mostar						
Course content	Week / shift		Topic				
	Day 1		Seminar: Types of Trial Designs Practical: Registering clinical trials				
	Day 2		Seminar: Randomization and Masking Practical: Good Clinical practice				
	Day 3		Seminar: Outcomes and Analysis Practical: Journal club				
	Day 4		Seminar: Reporting results Practical: CONSORT statement				
	Day5		Seminar: Beyond clinical trials Practical: Choosing evidence for clinical practice				
Language	English						
E-learning	Classes are conducted in person. If necessary, lectures, seminars and exercises can be combined (in person and online) or completely online via e-learning platforms (Google-Meet) up to max 20%.						
Teaching methods	Teaching, interactive and active-experiential.						
Types of assessment (indicate - Bold)							
Type of pre-examination obligation					Type of exam		
midterm	seminar paper	essay/report	practical/project task	other	written exam	oral exam	practical
Allocation of ECTS credits and share in the grade							
Student obligations		Learning outcome code		Hours of workload		Share in ECTS	Share in grade

Class attendance and participations		15	0.6								
Practical/project task	IU-MFMSEI05-4 IU-MFMSEI05-4	10	0.3	20%							
Written exam	IU-MFMSEI05-1 IU-MFMSEI05-2 IU-MFMSEI05-3	20	0.6	80%							
In total		45	1.5	100%							
Method of calculating the final grade											
Evaluation is descriptive (pass/fail).											
Literature (indicate)	Title (title, author, year)	Edition		Language				Type of literature			
		own	other	Croatian	English	other	multilingual	book	article	script	other
Compulsory	Marušić M, editor. Principles of Research in Medicine. 2nd ed. Zagreb: Medicinska naklada; 2019.		x		x			x			
Additional	Course materials, available in SUMARUM	x									
Additional course information											