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| ***Name of the course*** | **Understanding Clinical Trials** | | | | | | | ***Code*** | | | MSESES05 |
| ***Type of study program:*** | Integrated university studies, Medicine | | | | | | | ***Year of study:*** | | | 3 |
| ***Credits (ECTS):*** | 1.5 | | ***Semester:*** | | | VI | | ***Number of hours per semester***  ***(l+s+e)*** | | | 25  (0+15+10) |
| ***Status of the course:*** | elective | | ***Preconditions:*** | | | According to the Rulebook | | ***Comparative conditions:*** | | | / |
| ***Access to course:*** | Third year medical students | | | | | | | ***Hours of***  ***instructions:*** | | | According  to schedule |
| ***Course teacher*:** | | | Prof. Ana Marušić MD, PhD | | | | | | | | |
| ***Consultations:*** | | | As agreed with students | | | | | | | | |
| ***E-mail address and phone number:*** | | | [ana.marusic@mefst.hr,](mailto:ana.marusic@mefst.hr) +385 98 508 647 | | | | | | | | |
| ***Associate teachers:*** | | | Nensi Ćaćić, MD  Jakov Matas, MD | | | | | | | | |
| ***Consultations:*** | | | As agreed with students | | | | | | | | |
| ***E-mail address and phone number:*** | | | [nensi.cacic@mefst.hr](mailto:nensi.cacic@mefst.hr)  [jakov.matas@mefst.hr](mailto:jakov.matas@mefst.hr) | | | | | | | | |
| ***The aims of the course:*** | The aim of the course is to enable students with skills and knowledge necessary for understanding clinical trials. | | | | | | | | | | |
| ***Learning outcomes (general and specific competences):*** | General outcomes   * To describe the importance of clinical trials * To describe the basic principles of good clinical practice   Specific outcomes   * To interpret intention-to-treat and per-protocol analysis * To identify most important outcomes of clinical trials * To list and provide examples of different clinical trial designs * To recognize the importance of randomization and blinding | | | | | | | | | | |
| ***Course content (Syllabus):*** | | Each day will start with seminars, followed by exercises (practicals).  Seminars:  Seminar: Types of Trial Designs  Seminar: Randomization and Masking  Seminar: Outcomes and Analysis  Seminar: Reporting results  Seminar: Beyond clinical trials  Practicals:  Practical: Registering clinical trials  Practical: Good Clinical practice  Practical: Journal club  Practical: CONSORT statement  Practical: Choosing evidence for clinical practice | | | | | | | | | | |
| ***Format of instruction (mark in bold)*** | | Lectures | | | **Exercises** | | | **Seminars** | | | Independent assignment s | |
| **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 *European system of points* | | | | | | | | | | | | |
| **STUDENTS RESPONSIBILITIES** | | | **HOURS** | | | **PROPORTIONS OF ECTS CREDITS** | | | | **PROPORTION S OF MARK** | | |
| Class attendance and participations | | | 25 | | | 0.9 | | | | 0% | | |
| Seminar essay | | | 10 | | | 0.3 | | | | 0% | | |
| Written exam | | | 10 | | | 0.3 | | | | 100% | | |
| Total | | | 45 | | | 1.5 | | | | 100% | | |
| Further clarification:  Evaluation is descriptive (pass/fail) | | | | | | | | | | | | |
| ***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.  Course materials, available in SUMARUM. | | | | | | | | | | |
| ***Additional information about the course*** | | Means of course quality control:  Student questionnaire  Quality analysis by students and teachers  Analysis of student passing rate  Office for course quality control report  Self-evaluation and out of institutional evaluation (visits by quality control teams) | | | | | | | | | | |

Annexes: calendar classes

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| ***The number of teaching units*** | **TOPICS AND LITERATURE** |
| ***I.*** | Title: What is a clinical trial? |
| Short description: Understanding study designs, registration of clinical trials, transparency |
| Literature: Required literature, course materials in SUMARUM |
| ***II.*** | 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 |
| ***III.*** | 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 |
| ***IV.*** | Title: Reporting clinical trials |
| Short description: Reporting guidelines for clinical trials, CONSORT checklist |
| Literature: Required literature, course materials in SUMARUM |
| ***V.*** | Title: Beyond clinical trials |
| Short description: Translation to practice, meta-analysis, clinical practice guidelines |
| Literature: Required literature, course materials in SUMARUM |