

MODULE OUTLINE

(1) GENERAL INFORMATION

SCHOOL	School of Science and Technology		
PROGRAM COURSE	Precision Medicine and Novel Therapies (PRETH)		
LEVEL OF STUDY	Postgraduate		
MODULE CODE	PRETH53	YEAR OF STUDY	1 st (2 nd semester)
MODULE TITLE	Bioethics and clinical trials		
INDEPENDENT TEACHING ACTIVITIES <i>in case credits are awarded for separate components/parts of the course, e.g. in lectures, laboratory exercises, etc. If credits are awarded for the entire course, give the weekly teaching hours and the total credits</i>		HOURS	CREDITS
Hours per week (28-29 hours) x 13 weeks		375	15
MODULE TYPE Compulsory, Optional, Optional mandatory	Compulsory		
PREREQUISITE MODULES:	NO		
LANGUAGE OF INSTRUCTION AND EXAMS:	English		
THE MODULE IS OFFERED TO ERASMUS STUDENTS	Yes		
MODULE WEBSITE (URL)	https://www.eap.gr/en/preth/ Each module has its own space in the Learning Management System of EAP, with controlled access (use of code) for students and teaching staff. https://courses.eap.gr/course/view.php?id=337		

(2) LEARNING OUTCOMES

Learning Outcomes

The course learning outcomes, specific knowledge, skills and competences of an appropriate (certain) level, which students will acquire upon successful completion of the course, are described in detail. It is necessary to consult:

APPENDIX A

- Description of the level of learning outcomes for each level of study, in accordance with the European Higher Education Qualifications' Framework.
- Descriptive indicators for Levels 6, 7 & 8 of the European Qualifications Framework for Lifelong Learning and

APPENDIX B

- Guidelines for writing Learning Outcomes

Learning Outcomes

The trainees are expected to:

- Describe main principles for guiding the conduct of ethical research and clinical trials
- Refer to the social and clinical value of exposing human subjects to the risk and burden of research
- Describe the potential conflicts of interest of a study
- Describe the process of Informed consent for participants in a study
- Refer to the respecting rules for potential and enrolled subjects

General Competences

Taking into consideration the general competences that students/graduates must acquire (as those are described in the Diploma Supplement and are mentioned below), at which of the following does the course attendance aim?

Search for, analysis and synthesis of data and information by the use of appropriate technologies,	Project planning and management
Adapting to new situations	Respect for diversity and multiculturalism
Decision-making	Environmental awareness
Individual/Independent work	Social, professional and ethical responsibility and sensitivity to gender issues
Group/Team work	Critical thinking
Working in an international environment	Development of free, creative and inductive thinking
Working in an interdisciplinary environment
Introduction of innovative research	(Other.....citizenship, spiritual freedom, social awareness, altruism etc.)

Expected general skills that the trainees will acquire:

- Work in an international environment
- Work in an interdisciplinary environment
- Production of new research ideas
- Search, analysis and synthesis of data and information, using the necessary technologies
- Promoting free, creative and inductive thinking

(3) MODULE CONTENT

The aim of clinical research is to develop knowledge and improve human health. Researchers who participate in clinical research must be sensitive to ethical concerns. Guidelines that did not previously exist have been recently well-established. However, ethical values change over time, and it is important to continuously upgrade, there is not always consensus on what counts as ethical research and finally, multiple interests — medical, personal, political,

military, and commercial — have led researchers to conduct transgressive studies so far. This module focuses in influential codes of ethics and regulations that guide ethical clinical research, such as Declaration of Helsinki (2000), CIOMS (2002) etc. Comprehensive sources of ethical guidance main principles will be described as guiding for the performance of ethical research. Reference will also be made to the regulations governing the clinical trials taking place.

- Bioethics
- Clinical trials legislation, registration procedures etc
- Clinical trials design and implementation
- Adaptive designs: i.e. basket, umbrella, e-trials
- Investigator Sponsoring Clinical Trials
- Non interventional clinical studies
- Biomarkers-based population clinical studies
- Real World Data studies

(4) TEACHING METHODS - ASSESSMENT

<p>MODES OF DELIVERY <i>Face-to-face, in-class lecturing, distance teaching and distance learning etc.</i></p>	<p>Distance learning by conducting three Group Counseling Meetings (GCMs) during the academic semester on weekends. Five-days face-to-face lab training at the end of the semester, with 10 hours/day of lab practice.</p>															
<p>USE OF INFORMATION AND COMMUNICATION TECHNOLOGY <i>Use of ICT in teaching, Laboratory Education, Communication with students</i></p>	<p>In GCMs and teaching we use:</p> <ul style="list-style-type: none"> - Remote meetings tools (Webex, Cisco etc.) - Presentation software (e.g. power point, animations etc.) - Specialized software in the subjects under study (NCBI PubMed, NCBI Blast, EndNote, etc.) <p>In addition, students use office automation tools, web browsers and e-readers for digital books.</p> <p>Distance learning and communication with the students is supported by:</p> <ul style="list-style-type: none"> - the (Hellenic Open University (HOU) digital platform http://courses.eap.gr (course information, educational material postings, announcements, messages, exam results, user groups, discussion forums, etc.). - Electronic mail (e-mail) 															
<p>MODULE DESIGN <i>Description of teaching techniques, practices and methods: Lectures, seminars, laboratory practice, fieldwork, study and analysis of bibliography, tutorials, Internship, Art Workshop, Interactive teaching, Educational visits, projects, Essay writing, Artistic creativity, etc.</i></p> <p><i>The study hours for each learning activity as well as</i></p>	<table border="1"> <thead> <tr> <th><i>Activity/Method</i></th> <th><i>Semester workload</i></th> </tr> </thead> <tbody> <tr> <td>3 GCMs x 4 hours</td> <td>12</td> </tr> <tr> <td>2 educational activities (x 10 hours)</td> <td>20</td> </tr> <tr> <td>2 Semester Assignments (x 30 hours)</td> <td>60</td> </tr> <tr> <td>Tutoring sessions</td> <td>5</td> </tr> <tr> <td>Final examination</td> <td>4</td> </tr> <tr> <td>Individual study</td> <td>274</td> </tr> </tbody> </table>	<i>Activity/Method</i>	<i>Semester workload</i>	3 GCMs x 4 hours	12	2 educational activities (x 10 hours)	20	2 Semester Assignments (x 30 hours)	60	Tutoring sessions	5	Final examination	4	Individual study	274	
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<i>the hours of selfdirected study are given following the principles of the ECTS.</i>		
	Total module workload (hours)	375
<p>STUDENT PERFORMANCE EVALUATION/ASSESSMENT METHODS</p> <p><i>Detailed description of the evaluation procedures:</i></p> <p><i>Language of evaluation, assessment methods, formative or summative (conclusive), multiple choice tests, short- answer questions, open-ended questions, problem solving, written work, essay/report, oral exam, presentation, laboratory work, other.....etc.</i></p> <p><i>Specifically defined evaluation criteria are stated, as well as if and where they are accessible by the students.</i></p>	<p>Student Evaluation – Module Grade</p> <p>a. Two (2) multiple-choice (quiz) educational activities (Q), which contribute equally to the final grade with a value of 5% each.</p> <p>b. Two (2) Semester Assignments (A) which contribute equally to the final grade with a value of 15% each.</p> <p>The scoring of educational activities and assignments is activated only if the student succeeds an overall score equal to or above the base (≥ 5) in the final or repeat exams.</p> <p>c. Final or repeat exams (E) contributing to the final grade of the module by 60%.</p> <p>The Final Grade of the module, within scale 1-10 (10 is the excellent), is calculated as follows: Final Grade=(Q1x0.05) + (Q2x0.05) + (A1x0.15) + (A2x0.05) + (Ex0.6)</p> <p>Language of evaluation: English</p> <p>The evaluation criteria are explicitly mentioned in the web published study guide (https://www.eap.gr/education/odigos-spoudwn-eap/), as well as in the educational platform (http://courses.eap.gr), with controlled access (use of code) for students.</p>	

(5) SUGGESTED BIBLIOGRAPHY

Text books and e-books

1. ICH-GCPs ICH harmonised guideline integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) ICH Consensus Guideline <https://ichgcp.net>
2. Adaptive designs in clinical trials: why use them, and how to run and report them *BMJ Medicine* volume 16, Article number: 29 (2018)

Related scientific journals

Current scientific literature from PUBMED database