

SEA-EU micro credential course sheet

Course offers for the SEA-EU micro-credential Programmes on Future Skills or Sustainability Studies

General Information

Course Title		Code
AI-Driven Medicine: Data Governance, Regulatory Challenges and Ethical Frontiers		
Course teacher		
Prof. Franco Trubiani – franco.trubiani@uniparthenope.it Associated Teacher: Prof. Ana Marušić - ana.marusic@mefst.hr		
Organiser/Contact person		
Prof. Franco Trubiani – franco.trubiani@uniparthenope.it		
Credits (ECTS)	Workload	
3	1 ECTS = 25 to 30 h Workload, Including 24h contact hours and 66h self-instructed learning.	
Language of instruction		
English		
Mode of provision		
☐ Physical attendance of students: 100% ☐ Physical attendance of students: partly required ☐ remote attendance possible ☒ online 100%		
Percentage of e-learning (0-100%)		
100%		
Short course description (for dissemination to students)		
This course originates within the framework of a SEED SEA-EU collaborative initiative developed jointly by the Department of Economic and Legal Studies of the University of Naples Parthenope and the Medical School of the University of Split. Conceived as an interdisciplinary educational project within the broader academic network of the SEA-EU Alliance, the course aims to explore the transformative role of artificial intelligence in contemporary medicine, with particular attention to the governance of health data, emerging regulatory frameworks, and the ethical challenges posed by data-driven healthcare. The course provides students with a comprehensive understanding of how AI technologies are reshaping clinical decision-making, diagnostics, personalized medicine, and healthcare management. At the same time, it critically examines the legal and ethical implications associated with the use of large-scale health datasets, algorithmic decision systems, and digital health platforms. The program begins with an introduction to the technological foundations of AI in medicine, including machine learning applications in clinical practice and biomedical research. It then moves		

to the analysis of health data ecosystems, addressing issues such as data collection, interoperability, data sharing infrastructures, and the governance of medical information in research and clinical contexts.

A significant part of the course with the participation of external experts and professors is devoted to the regulatory landscape governing AI and health data in Europe, including the legal principles of data protection, medical data processing, and digital health regulation under European law. Particular attention is paid to the implications of the European Health Data Space (EHDS) and the emerging framework established by the European Union Artificial Intelligence Act (AIA) for medical AI systems.

The course also explores the ethical frontiers of AI-driven medicine, including issues of algorithmic transparency, accountability in automated decision-making, bias in medical datasets, patient autonomy, and the impact of predictive technologies on the doctor-patient relationship. Through interdisciplinary dialogue between legal scholars, economists, and medical experts, students will develop a critical perspective on the governance of digital health technologies.

The course is designed for students and young researchers interested in digital health, health law, medical innovation, and data governance, and aims to foster interdisciplinary competencies necessary to navigate the rapidly evolving landscape of AI-enabled healthcare.

Organisational Information

Course format/teaching and learning method (see SEA-EU list of teaching and learning methods at the end of this document)
Lecture & Seminar
Max. number of participants
30
Course enrolment
Students from a SEA-EU University apply for this course via https://studfeedback.uni-kiel.de/evasys/online.php?p=T7LGP (closing date 16 th September 2026) For any request, please write to Mariavittoria Volpe or Marina Federico: mariavittoria.volpe001@studenti.uniparthenope.it marina.federico@collaboratore.uniparthenope.it
Course fees
Enrollment in this course is free of charge.
Enrolment requirements
Study level ☒ Bachelor (level 6) ☐ Master (level 7) ☐ PhD/Doctorate (level 8) Entry level of language proficiency: B2 level (English)
Course dates, period and time / Link to the University's website for the course
The course will take place from 21 September to 27 October (Class Time: 3:00 PM – 5:00 PM on Microsoft Teams - Team Code)

with classes held every Monday and Tuesday according to the following schedule:

- Monday, 21 September (Lecture) European Regulation of AI in Healthcare: Balancing Innovation and Fundamental Rights
- Tuesday, 22 September (Lecture) Algorithms and Medical Decision-Making: Liability, Explainability and Transparency
- Monday, 28 September (Lecture) Introduction to AI: Concepts and Applications
- Tuesday, 29 September (Seminar) Introduction to AI: Practical Exercises
- Monday, 5 October (Lecture) AI in Clinical Practice and Biomedical Research
- Tuesday, 6 October (Seminar) Informed Consent and the Doctor–Patient Relationship in the Age of AI
- Monday, 12 October (Lecture) Ethical Challenges in AI-Driven Medicine
- Tuesday, 13 October (Seminar) Ethical Challenges in AI-Driven Medicine
- Monday, 19 October (Lecture) The European Union’s role in Global Health
- Tuesday, 20 October (Seminar) Data Governance in Digital Health: Ownership, Access, and Sharing of Clinical Data
- Monday, 26 October (Lecture) AI in Scientific Publishing: Ethics, Policies, and Best Practices
- Tuesday, 27 October (Final discussion)

Other remarks

The course is also open for Master & PhD Students

Learning Conditions

Course content

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Learning outcomes (knowledge, skills, attitudes)

By the end of the course, students will be able to:

Understand the technological foundations and principal applications of artificial intelligence in contemporary medical practice and biomedical research.

Analyse the role of health data in AI-driven medicine and the main models of data governance in healthcare systems.

Identify the legal frameworks regulating the processing and use of medical data in the European context, with particular reference to the European Health Data Space Regulation.

Evaluate the regulatory implications of AI-based medical technologies under emerging European legislation, including the European Union Artificial Intelligence Act.

Assess ethical challenges related to algorithmic decision-making in medicine, including transparency, bias, accountability, and patient autonomy.

Critically examine the impact of AI systems on the doctor-patient relationship and on clinical responsibility.

Interpret and discuss case studies concerning the deployment of AI tools in diagnostics, predictive medicine, and healthcare management.

Develop interdisciplinary analytical skills integrating legal, ethical, economic, and medical perspectives.

Formulate informed evaluations of regulatory and governance models for digital health technologies.

Engage in academic and policy-oriented debates on the future development of AI-driven healthcare systems in Europe.

Student activities

The course combines lectures, interactive seminars, and collaborative learning activities designed to encourage critical reflection and interdisciplinary dialogue. Students will engage in guided discussions on the legal, ethical, and regulatory implications of artificial intelligence in healthcare, analysing contemporary challenges related to medical data and digital health technologies.

A central component of the course will consist of case study analysis, in which students will examine practical examples concerning the deployment of AI systems in clinical diagnostics, predictive medicine, and healthcare management. Through these exercises, participants will develop the ability to interpret regulatory frameworks and evaluate ethical dilemmas arising from algorithmic decision-making in medicine.

Students will also participate in group work and short presentations, focusing on specific topics such as data governance models, regulatory approaches to medical AI, and the implications of European legislation including the EHDS and Artificial Intelligence Act.

Attendance policy

Regular attendance is strongly recommended in order to ensure active participation in lectures, seminars, and collaborative learning activities. Given the interdisciplinary and discussion-based structure of the course, students are expected to attend classes consistently and to contribute to classroom dialogue and group work.

Students are required to attend at least 70% of the scheduled sessions in order to successfully complete the course.

Assessment Methods (see SEA-EU list of assignments in this document)

Assignment

Grading

☐ graded x non-graded (pass/fail)

Study materials/Course literature

F. Pasquale, The black box society, Harvard University Press, 2015, pp. 1-18.

Vv. Aa., Artificial Intelligence in Healthcare and the Protection of Health as a Fundamental Right, 2025, pp. 123-148.

F. Trubiani, Health Data Governance: Towards the Creation of an International And European Digital Sharing Ecosystem, en Nuovo dir. civ., n. 1/2026, pp. 101-123.

Students can use teachers' PowerPoint presentations as a valuable study aid for this course. Additional study materials and further specific references will be provided during lectures.

Linkage to SEA-EU micro-credential Programmes

Linked to micro-credential programme and category (choose only one category) (see Future Skills Framework or Sustainability Studies Framework)

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|---|---|
| ☐ Future Skills | x Sustainability Studies |
| ☐ Higher order thinking competences | ☐ Sustainability as a concept |
| ☐ Self competences | ☐ Sustainable economy |
| ☐ Social and communication competences | x Peace, justice and inclusion |
| ☐ Transformative competences | ☐ Life on land and in water |
| ☐ Digital and media competences | ☐ Climate change |
| | ☐ Sustainable cities and local communities |
| | ☐ Industry and Innovation for Sustainability |

Linked Competence(s)/Issue(s) in your chosen category you will provide with your teaching

Democracy and citizenship

International and Environmental Law

Future Skills Framework

Meta category	Competences
Higher order thinking competences	☐ Adaptability competences ☐ Problem solving competences ☐ Critical and Systems thinking competences
Self competences	☐ Active Learning competences ☐ Self-awareness competences ☐ Complexity and ambiguity competences
Social and communication competences	☐ Collaboration and networking competences ☐ Communication competences ☐ Leadership competences
Transformative competences	☐ Entrepreneurship competences ☐ Citizenship competences ☐ Global awareness competences
Digital and media competences	☐ Data Literacy competences ☐ Media literacy competences ☐ Digital collaboration competences

For details and learning outcomes see SEA-EU micro-credentials Sustainability Studies Framework document

Sustainability Studies Framework

Meta-category	Issues
Sustainability as a concept	☐ Key concepts and principles of sustainability ☐ Evolution of the concept of sustainable development ☐ Introduction to corporate sustainability ☐ Implementing sustainability

Sustainable economy	☐ Responsible and sustainable production and consumption ☐ Corporate Social Responsibility and decent work ☐ Green, Circular and Blue Economy
Peace, justice and inclusion	☐ Resilience, Preparedness and Emergency Management ☐ Building equitable, inclusive societies ☐ Democracy and citizenship ☐ International and Environmental Law
Life on land and in water	☐ Sustainable food production ☐ Public health, poverty and well-being ☐ Biodiversity in ecosystems ☐ Hydrosphere, Oceans and Water Management
Climate change	☐ Consequences of climate change on the ocean ☐ Greenhouse effect ☐ Social, cultural and economic consequences of climate change
Sustainable cities and local communities	☐ Sustainable city planning ☐ People, Resources and Environment ☐ Sustainable tourism, travel and mobility ☐ Waste and recycling
Industry and Innovation for Sustainability	☐ Inclusive and sustainable innovation and industrialization ☐ Sustainable, innovative and resilient infrastructure development ☐ Clean Energy and Bioeconomy ☐ The sustainability of information and communication technology (ICT) including supply chains

For details and learning outcomes see SEA-EU micro-credentials Sustainability Studies Framework document

Teaching and learning methods:

Teaching method	Definition
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Fieldwork	Educational activities conducted outside the classroom, typically in real-world settings. It involves hands-on experience, data collection, or research in a specific field related to the course.
Lecture	A method of teaching where an instructor presents information to a large group of students. It is a one-way communication where the lecturer imparts knowledge and concepts.
Performance	A teaching method that involves students showcasing their skills or understanding through practical demonstrations, presentations, or performances, often related to the subject matter.
Practical Study-Unit	A study unit focused on hands-on application of theoretical knowledge, often involving practical exercises, experiments, or projects related to the course.
Practicum	Similar to an internship, a practicum is a hands-on learning experience in a professional setting, typically associated with teacher training or counselling programs.
Project	A collaborative or individual task requiring students to plan, execute, and present the results of an in-depth investigation or creative work related to the course.
Seminar	A small-group discussion or workshop led by a facilitator, where students actively engage with the material, discuss concepts, and share ideas. It encourages participation and critical thinking.
Tutorials	Small-group or one-on-one sessions where students receive personalised instruction, clarification of concepts, and guidance from a tutor or instructor. Tutorials supplement larger lectures and allow for individualised learning.

Methods of Assessment:

Teaching method	Definition
Analysis Task	A task which requires students to identify the primary elements of a problem or task at hand, and then outline the steps and skills required to ensure that the task is performed optimally.
Assignment	Normally an essay (or a set of written exercises) to be done away from the classroom and submitted by a set date.
Case Study (Exam conditions)	A research approach that is used to generate in-depth, multi-faceted understanding of a complex issue within a real-life context, which includes the application of discipline specific models, constructs and research literature..
Case Study (take home)	Students are required to work through a case study to identify the problem(s) and to offer potential solutions; useful for assessing students' understanding and for encouraging students to see links between theory and practice. Case studies could be provided in advance of a time-constrained assessment.
Classwork	Written or oral exercises carried out by students whilst in the classroom. Examples include: discussions, debates, translation exercises, etc.
Competencies	Refers to a continuous process which aims at building the student's capabilities (knowledge, skills and abilities), and assessing them against stated (professional) standards.

Essay	An analytical, interpretative, or critical piece of writing that expresses the writer's opinion in response to a set question, problem or issue.
Examination	A written assessment (using traditional pen and paper or a digital platform for the administration of the examination) which is carried out in a predetermined, restricted time span under invigilated conditions. This type of assessment is normally summative in nature.
Fieldwork	Work which is done on site to enable students to gain practical experience and knowledge through first hand observation.
Internship	An internship can be defined as any arrangement in which students are given opportunities to apply their learning and demonstrate their professional capabilities in the workplace, community context or other relevant settings. Assessment will be conducted by academic supervisors, industry supervisors or workplace mentors, or a combination of both.
Logbook	A systematic record of every phase of a project or placement activity.
Long Essay	An analytical, interpretative, or critical piece of writing that enables students to explore a specific subject area in some depth, explain theories and concepts; evaluate arguments, and express and support their own views and opinions.
Oral Examination	An examination during which students are required to verbally reply to questions posed to them in the spoken form.
	Students are asked to give an oral presentation on a particular topic for a specified length of time and could also be asked to prepare associated handout(s). Can usefully be combined with self- and peer-assessment.
Portfolio	A systematic and organised collection of a student's work that exhibits to others the direct evidence of a student's efforts, achievements, and progress over a period of time. It should include representative work, providing a documentation of the learner's performance and a basis for evaluation of the student's progress. Portfolios may include a variety of demonstrations of learning that have been gathered in the form of a physical collection of materials, videos, CD-ROMs, reflective journals, etc.
Poster	The production of a large print that can be displayed in a public space. It can include graphical images, text or a mixture of both and is usually designed with the intention of promoting an idea, event, product etc.
Report	A written document in which information is presented in an organised format. A report would normally include a descriptive statement, an account of the conditions that are observed, findings resulting from investigation and inquiry, and a conclusive summary in which the student puts forward any recommendations.
Research Paper	A research paper is an extended essay which is intended to assess the students' written, analytical, interpretative and argumentative skills, based on independent research.
Research Projects	Potential for sampling a wide range of practical, analytical and interpretative skills. Can assess wide application of knowledge, understanding and skills.
Research/Review Paper	A thorough and systematic analysis of published research findings, from which students are expected to provide new insights or interpretations about a topic or field of interest.
Role Play	Students write or give a presentation taking on a particular role, e.g. a journal reviewer/ editor, consultant, art critic etc. This type of assignment could be paired up with a grant application

	exercise.
Seminar Paper	A seminar paper is an advanced piece of writing which is intended to present an original piece of research to a group of peers.