



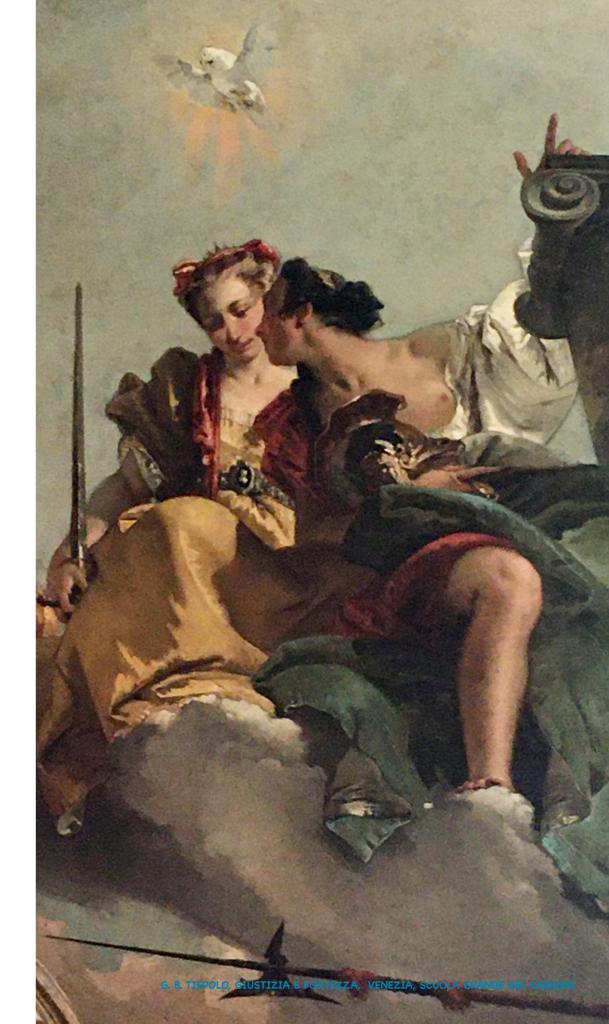
WINTER SCHOOL

"EUROPEAN HEALTH LAW & BIOTECHNOLOGY"

15-19 FEBRUARY 2021

HTTPS://ELATE.JUS.UNIPI.IT

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OVERVIEW

A joint initiative of the Department of Law and the Department of Information Engineering, EHL&BT is part of the Jean Monnet Module *European Health Law and Technology* (ELaTe), awarded in the framework of the Erasmus+ Programme (2020 - EAC-A02-2019-JMO).

The School will provide participants with an advanced understanding of the European regulatory framework of advanced biotechnologies.

Three academic credits (in accordance with the ECTS) will be awarded upon successful completion of the Course, which requires the attendance of at least 90% of classes and a final presentation. All classes will be taught in English.

Professionals, Master's degree students, PhD researchers with a background In legal or biotechnological disciplines are welcome to apply by 22 January 2021 exclusively <u>HERE</u>.

Academic Staff: V. Calderai, C. De Maria (coordinators), C. Angiolini, I. Chiesa, L. Di Pietro, F. Episcopo, T. Favaro, G. Fortunato, M. E. Lippi, E. Palmerini, G. Vozzi. Technological innovation in healthcare needs to conform to a complex normative matrix. In both legal and scientific education, it is essential to convey the importance of a cross-disciplinary approach and introduce a qualified public of learners to the most relevant competences in this field. This course—designed as an experiment in cross-fertilization between Law and Biomedical Engineering—offers a substantive introduction to these competences.

Participants will earn an understanding of the process of development, testing, marketing and diffusion of bioengineered health care applications within a European legal framework, with reference in particular to:

- (i) reduce liability risks, ensure compliance with relevant regulations, standards, and extant responsible research and innovation (RRI) requirements;
- (ii) embed fundamental rights protection within the development process of biotechnological innovation from research to application;
- (iii) adopt risk management and IPRs protection strategies.

Participants will join small cross-disciplinary teams. Each team will examine a case study, based on the problems faced by researchers and professionals in developing biotechnological applications. Team members assisted by tutors shall identify and discuss the relevant features of design specifications, and come up with solutions as much as possible built in the application. The team projects will be discussed in the final presentations.

TIMETABLE

	Monday, 15	Tuesday, 16	Wednesday, 17	Thursday, 18	Friday, 19
8:30 - 9:30	Winter School Presentation				
9:30-11:30	EU Legislation on Healthcare (1/2)	Technical Standard Organization	Ownership of Biological Materials and Personal Data	Trade secrets, Biotechnological inventions, Technological transfer	Fundamental Rights Protection and R&D
12:00-13:30	EU Legislation on Healthcare (2/2)	Case Studies: ISO 13485, ISO 10993, ISO 14972	Bioprinting of Human Tissues	Open Source Medical Devices	Group Working
14:30-16:30	Team Building	Group Working	Group Working	Group Working	Final Presentations
16:30-18:30	Group Working	Group Working	Intermediate presentations	Group Working	Final Presentations