UNIVERSITÀ DI PISA

DEPARTMENT OF INFORMATION ENGINEERING
DIPARTMENT OF LAW
RESEARCH CENTER ON HEALTH TECHNOLOGY ASSESSMENT (CIRHTA)

With the support of the Erasmus+ Programme of the European Union

Digital Winter School

THE LAW, ECONOMICS & ENGINEERING OF ADVANCED MEDICAL TECHNOLOGIES

17-28 January 2022

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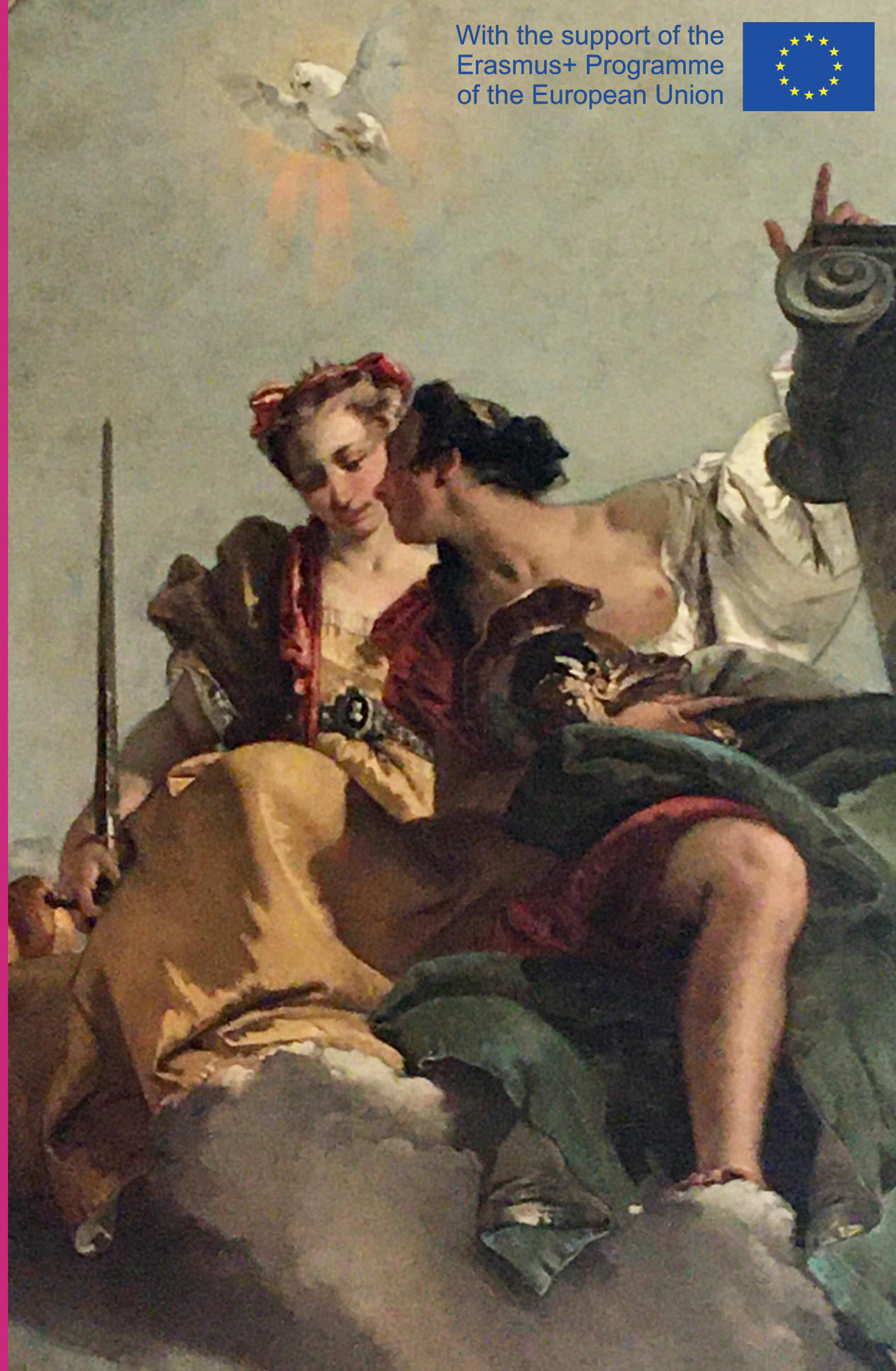

OVERVIEW

A joint initiative of the Department of Information Engineering, the Department of Law, and the Research Center on Health Technology Assessment this winter school 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 scientific, legal, and economical framework of the development of advanced biotechnologies.

Six 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 examination. All classes will be taught in English.

Professionals, PhD researchers and master students with a background In legal, economics, and bioengineering are welcome to apply.

https://www.unipi.it/index.php/engineering/item/20818-law-eco-eng-advanced-medical-technologies.

Academic Staff: C. De Maria, V. Calderai, L. Pellegrini, F. Episcopo, G. Fortunato, F. Coro, I. Chiesa M. E. Lippi, S. Lazzini, S. Tallarico, 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, Economics, 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 IPRs valorisation approach, identify the most appropriate business strategy and market placement.

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.

School at a glance

	Week 1: Safety-by-design medical devices				Week 2: Medical Device Market				
	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Day 8**	**Day9**
Morning	Introduction	Standardization	Risk based design	Informed Consent and Safety Requirements	Business models	Strategic Marketing	Operative Marketing	Ownership of Tissues and Data	The Liability Framework
	Certification of medical devices	**Keynote 1**		**Keynote 2**		**Keynote 4**	**Keynote 5**	Intellectual Property Right	**Keynote 6**
Afternoon	Team Building	Teamwork	ATMP	Teamwork	**Keynote 3**	Teamwork	Teamwork	Open Source Medical Devices	Final presentation
	Teamwork		Teamwork	Intermediate presentation 1	Teamwork		Intermediate presentation 2	Teamwork	

During the morning students will be provided with fundamentals of health law, medical device design and market analysis. Each afternoon, students, working in team, will apply what they learned in the morning on a specific medical device they selected

WEEK 1

Safety-by-design medical Devices

Day 1 - Monday Jan 17 2022

Time	Topic	Responsible
9:30 – 10:00	Introduction	V. Calderai, L. Pellegrini, C. De Maria, G. Vozzi, M. Mancino
10:00 – 11:00	Fundamentals on EU legislation on healthcare	V. Calderai
11:00 – 13:00	Medical Device Regulation 2017/745	C. De Maria
14:30 – 15:30	Project Based Learning and team Building	C. De Maria
15:30 – 18:30	Teamwork: selection and classification of a medical device	C. De Maria

Day 2 – Tuesday Jan 18 2022

Time	Topic	Responsible
10:00 – 11:00	Standardization: scope and rationale	F. Episcopo
11:00 – 13:00	Relevant standards for Medical Technologies	I. Chiesa, F. Coro
12:00 – 13:00	Keynote 1: Product liability in the medical devices sector after EU regulation 2017/745. Software-specific aspects.	S. Stefanelli (Studio Legale Stefanelli&Stefanelli)
14:30 – 18:30	Teamwork: Identification of relevant standards	C. De Maria

Day 3 – Wednesday 19 Jan 2022

Time	Topic	Responsible
10:00 – 13:00	Risk-based design	L. Di Pietro (1MED)
14:30 – 16:30	Advanced Therapy Medicinal Products	I. Chiesa, G.M. Fortunato
16:30 – 18:30	Teamwork: risk analysis	C. De Maria

Day 4 – Thursday 20 Jan 2022

Time	Topic	Responsible
10:00 – 12:00	Informed Consent and Safety Requirements	V. Calderai
12:00 – 13:00	Keynote 2: Trustworthy AI	A. Renda (University of Pisa) and A. Bertolini (Scuola Sant'Anna)
14:30 – 16:30	Teamwork	C. De Maria
16:30 – 18:30	Intermediate presentation 1	C. De Maria

Day 5 - Monday 24 Jan 2022

Time	Topic	Responsible
10:00 – 13:00	Business Models	L. Pellegrini, S. Lazzini
14:30 – 15:30	Keynote 3: Strategic & Operative Marketing in ASA Dental	D. Ciapponi (ASA Dental)
14:30 – 18:30	Teamwork	L. Pellegrini, S. Lazzini, S. Tallarico

Day 6 – Tuesday 25 Jan 2022

Time	Topic	Responsible
10:00 – 12:00	Strategic Marketing	L. Pellegrini, S. Lazzini
12:00 – 13:00	Keynote 4: Social Impact of Medical Technologies	G. Tomei (University of Pisa Pisa)
14:30 – 18:30	Teamwork	L. Pellegrini, S. Lazzini, S. Tallarico

Day 7 – Wednesday 26 Jan 2022

Time	Topic	Responsible
10:00 – 12:00	Operative Marketing	L. Pellegrini, S. Lazzini
12:00 – 13:00	Keynote 5: Strategic Marketing in Bracco Imaging	P. Castelli (Bracco)
14:30 – 18:00	Teamwork	
18:00 – 18:30	Intermediate presentation 2	L. Pellegrini

Day 8 – Thursday 27 Jan 2022

Time	Topic	Responsible
10:00 – 11:30	Tissues and Data Ownership	V. Calderai, M.E. Lippi
11:30 – 13:00	Intellectual property rights	M.E. Lippi
14:30 – 16:30	Open Source Medical Devices	M.E. Lippi, C. De Maria
16:30 – 18:30	Teamwork	

Day 9 – Friday 28 Jan 2022

Time	Topic	Responsible
10:00 – 12:00	The liability framework	F. Episcopo
12:00 – 13:00	Keynote 6: Towards a European Health Union: strengthening EU's competences in a disruptive technological environment	M. Kritikos (European Parliament Research Services)
14:30 – 16:30	Teamwork	V. Calderai
16:30 – 18:30	Final Presentation and closing remarks	V. Calderai, L. Pellegrini, C. De Maria, G. Vozzi, M. Mancino

WEEK 2

Medical Device Market