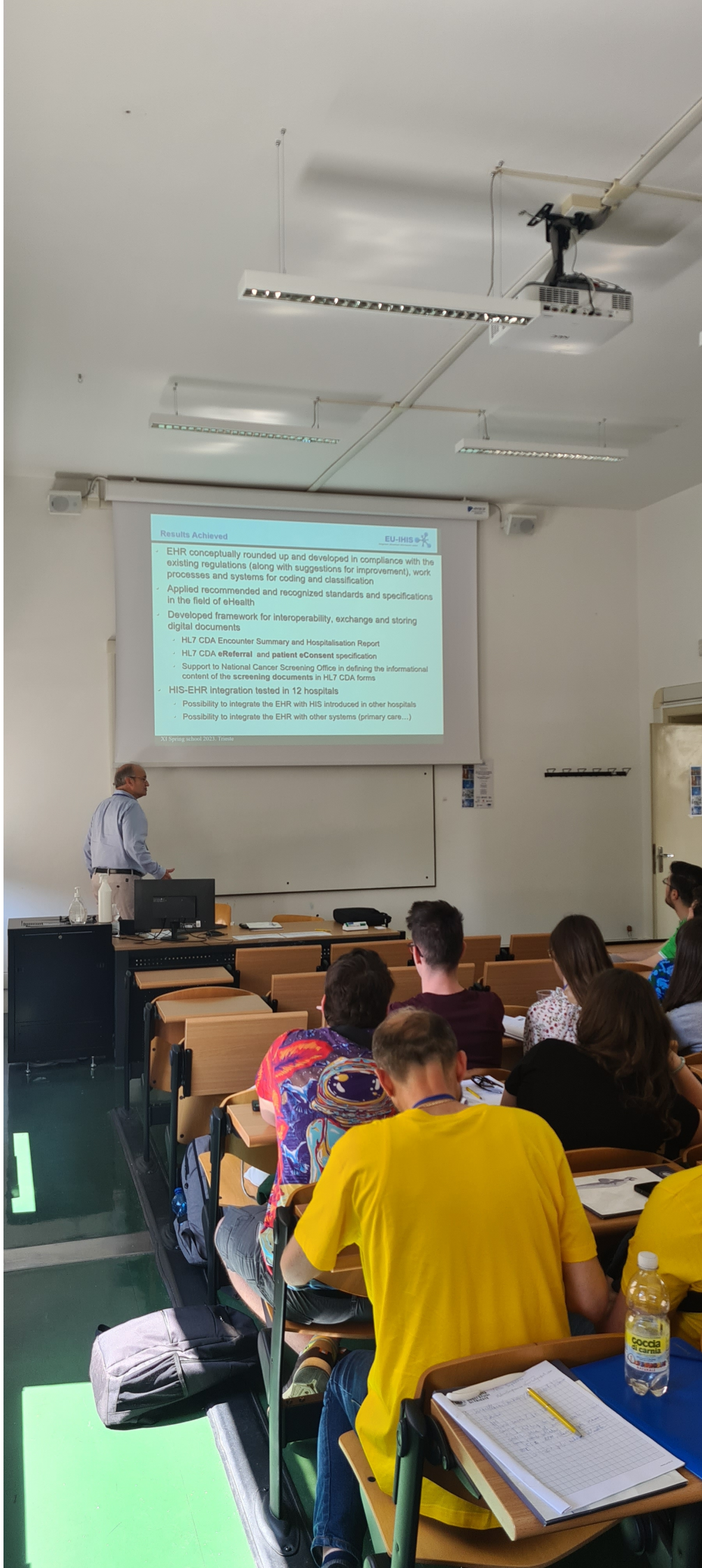


Results Achieved

EU-IHIS

- EHR conceptually rounded up and developed in compliance with the existing regulations (along with suggestions for improvement), work processes and systems for coding and classification
- Applied recommended and recognized standards and specifications in the field of eHealth
- Developed framework for interoperability, exchange and storing digital documents
 - HL7 CDA Encounter Summary and Hospitalisation Report
 - HL7 CDA eReferral and patient eConsent specification
 - Support to National Cancer Screening Office in defining the informational content of the screening documents in HL7 CDA forms
- HIS-EHR integration tested in 12 hospitals
 - Possibility to integrate the EHR with HIS introduced in other hospitals
 - Possibility to integrate the EHR with other systems (primary care...)

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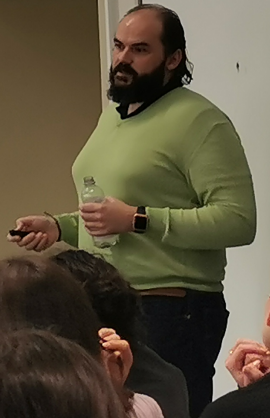
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MedTech Digital Transformation

- Connectivity
- Data Management
- Digital Twins
- Software as Medical Device (SaMD)





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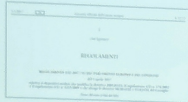
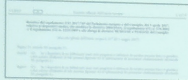
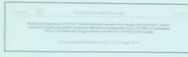
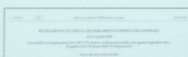
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The evolution of Regulation (EU) 2017/745

	Regulation 2017/745 published in EU Official Journal 5th May 2017
	Corrigendum of 3rd May 2019 (formal errors, various corrections)
	Corrigendum of 27th December 2019 (IMPORTANT: inclusion of Class I MD in the transition rules of Art. 120)
	Regulation 2020/561 published in EU Official Journal 24th April 2020 (application date moved to May 2021)




















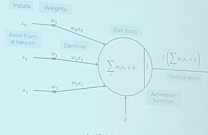




Convolutional Neural Networks Artificial Neurons



Biological Neuron




Artificial Neuron

In a biological neuron, the dendrites receive input signals, the cell body performs a summation function and, if the final sum is above a certain threshold, the neurons output an action potential sending a spike along their axon.

An artificial neuron receives one or more inputs and computes its output by a non-linear function of the weighted sum of its inputs. Each input has a weight that adjusts during learning, increasing or decreasing the strength of a connection.



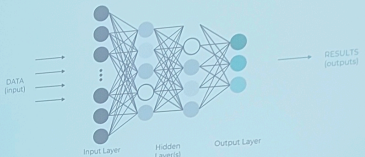
Convolutional Neural Networks
Artificial Neural Networks (ANNs)



- In an ANN, artificial neurons are aggregated into layers: the signal goes from the input layer to the output layer, after passing one or more hidden layers.
- Different layers may perform different kind of transformation on their inputs.



Convolutional Neural Networks
Artificial Neural Networks (ANNs)



DATA (input)

Input Layer

Hidden Layer(s)

Output Layer

RESULTS (output)

- In an ANN, artificial neurons are aggregated into layers: the signal goes from the input layer to the output layer, after traversing one or more hidden layers.
- Different layers may perform different kind of transformation on their inputs.

ZEERO





Regulation (EU) 2017/746 –
In vitro diagnostic medical devices

Official Journal of the European Union

L 117/176 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 3 April 2017
on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision
2010/227/EU
(Text with EEA relevance)

We'll not detail the Regulation (EU) 2017/746 on in vitro diagnostic
medical devices




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
REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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