UNIVERSITÀ DI PAVIA
Department of Electrical, Computer and Biomedical Engineering

BIO-MEDICAL INFORMATICS
"Mario Stefanelli"

Steering AI: Legal Challenges and Ethical Standards from an Engineering Perspective

Thursday 18 April 2024

AI applications in healthcare

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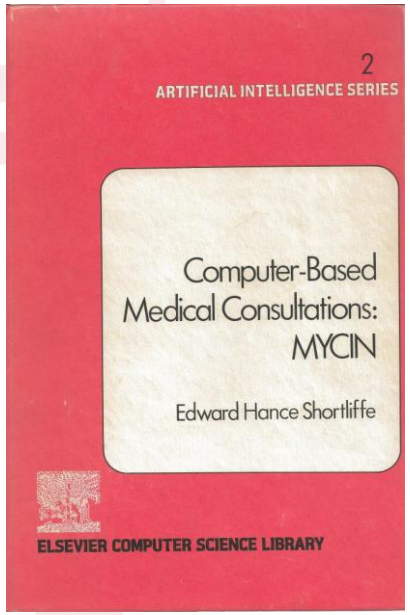
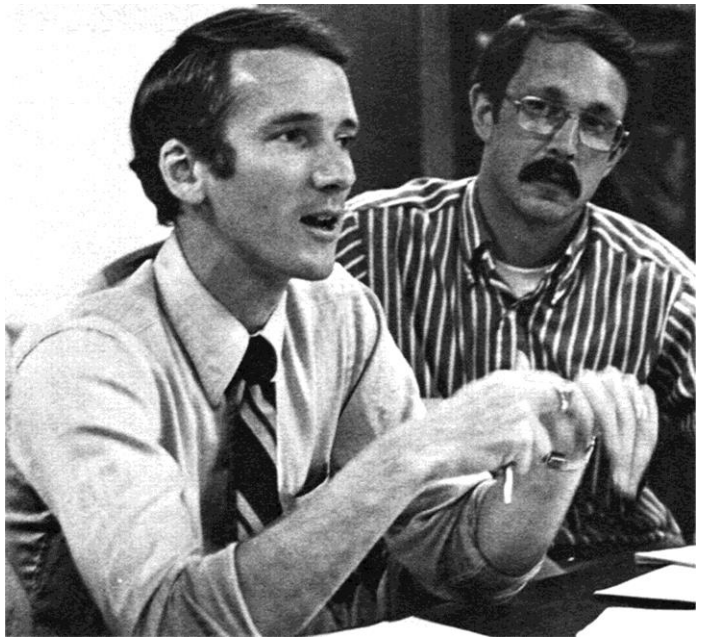
AI in Biomedical Applications

End of the 70s: first expert systems (Stanford)

We develop systems that emulate human reasoning, by representing in the system the existing, explicit knowledge directly elicited from the domain expert





Ted Shortliffe and **Bruce Buchanan**

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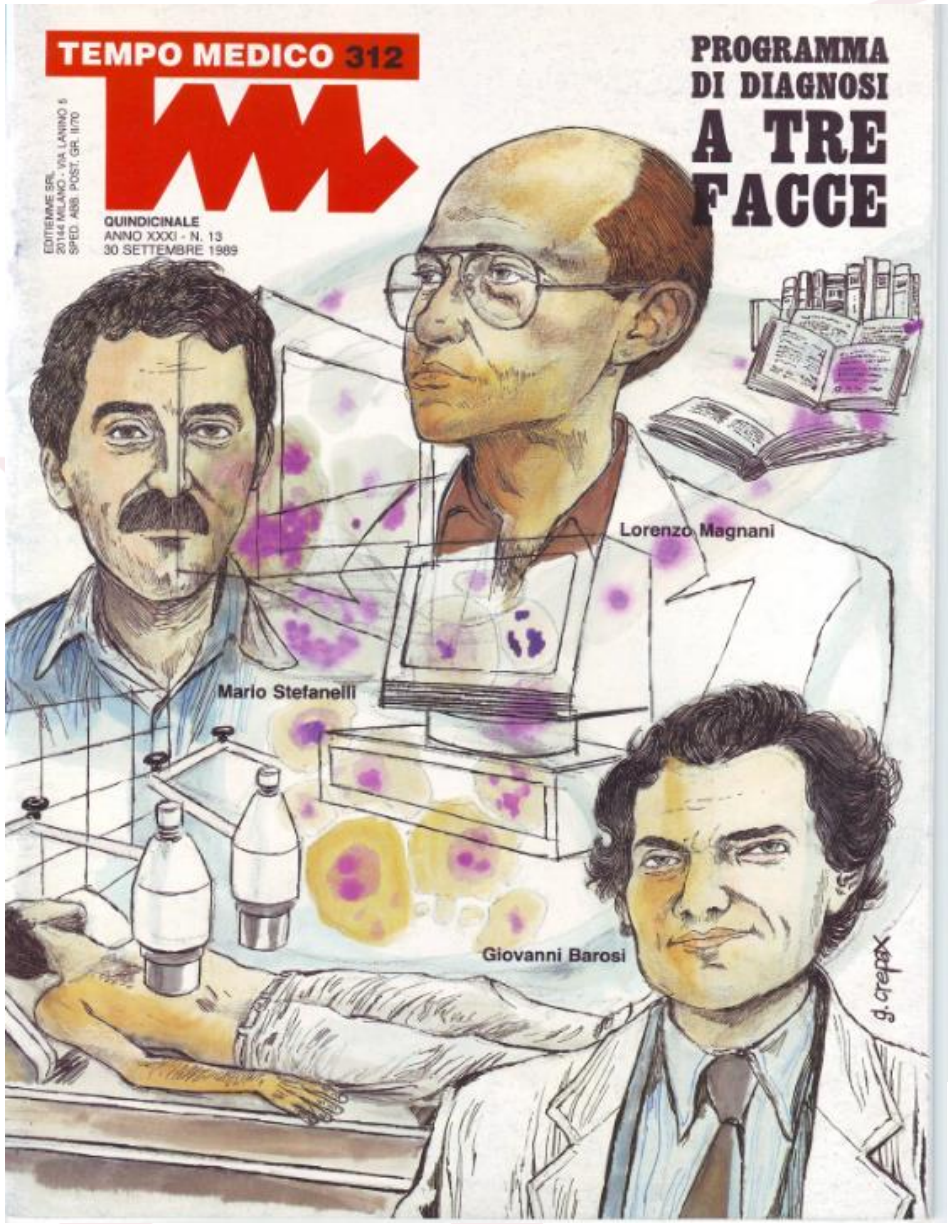
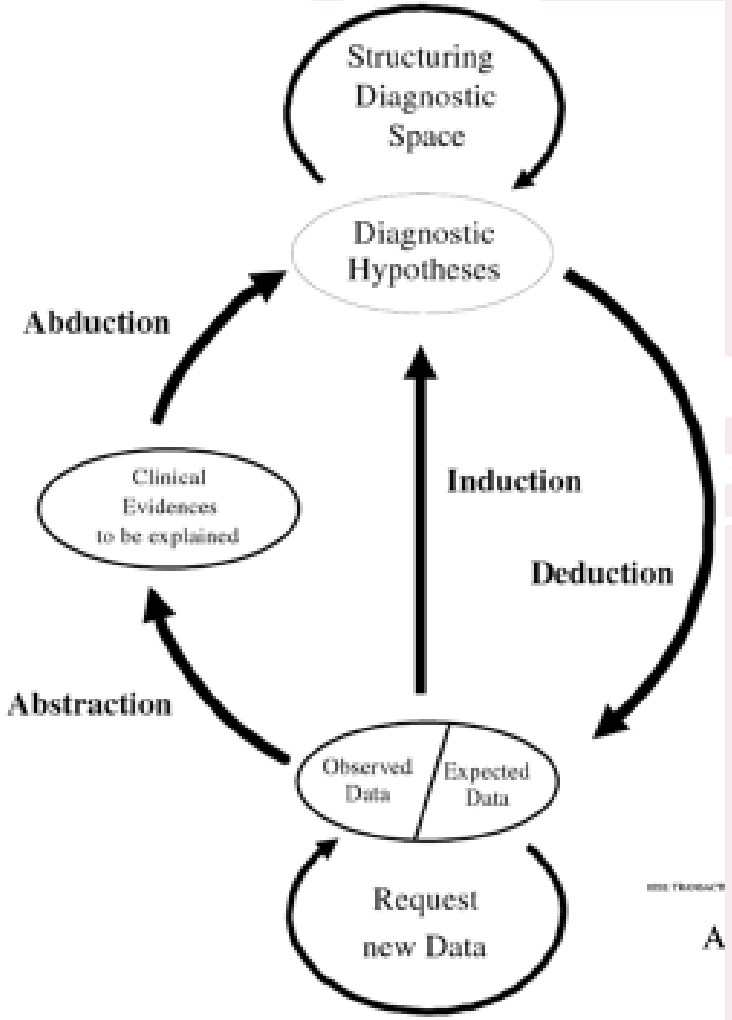
Shortliffe EH, Davis R, Axline SG, Buchanan BG, Green CC, Cohen SN. Computer-based consultations in clinical therapeutics: explanation and rule acquisition capabilities of the MYCIN system. Comput Biomed Res. 1975

A theoretical framework for designing KB systems





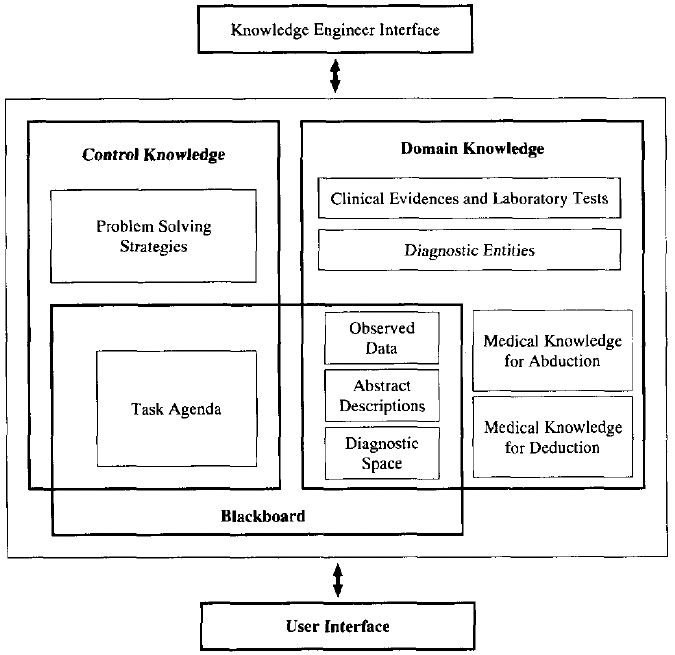
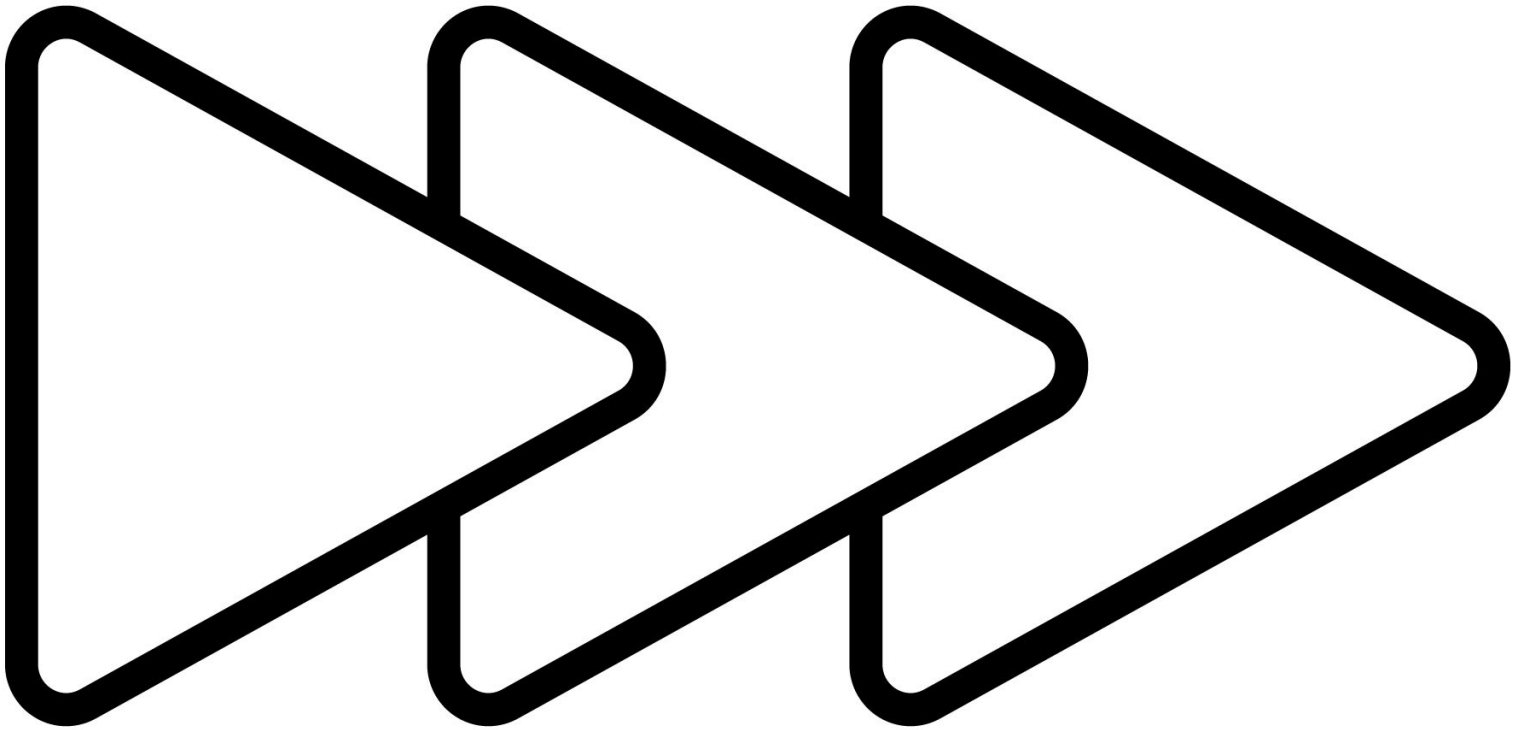


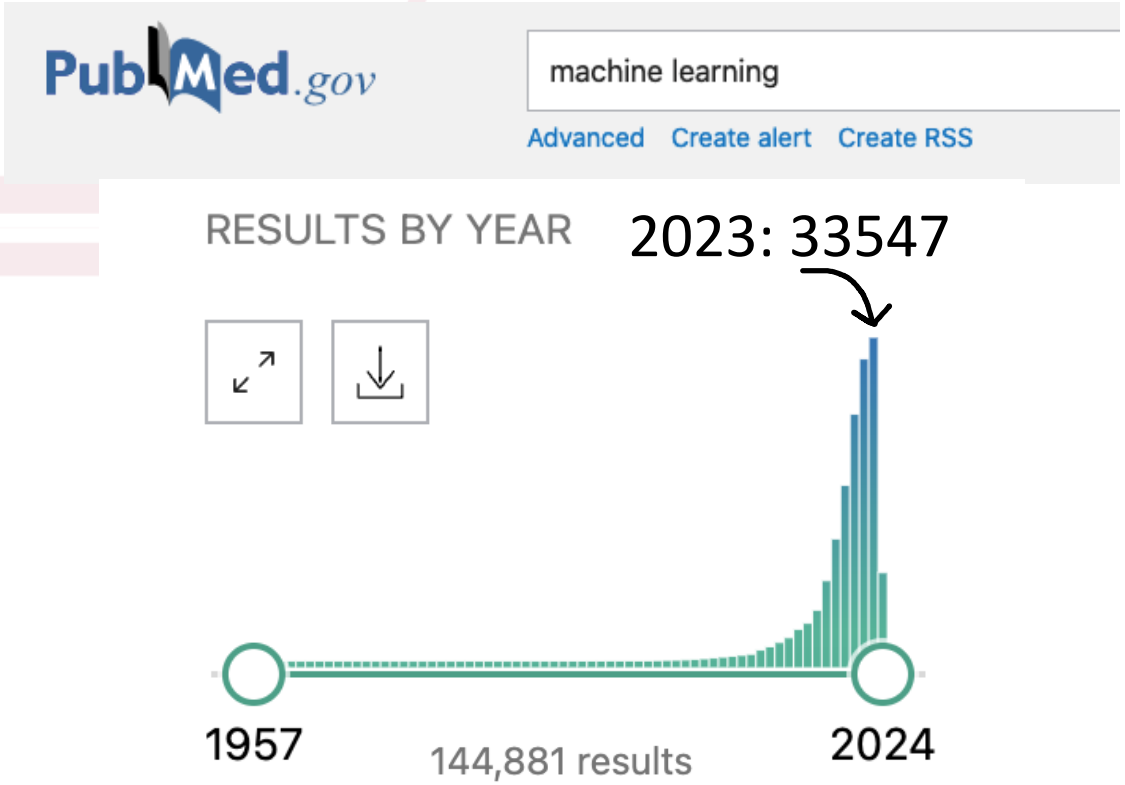
Fig. 5. The blackboard architecture of NEOANEMIA.

Barosi G, Magnani L, Stefanelli M. Medical diagnostic reasoning: epistemological modeling as a strategy for design of computer-based consultation programs. Theor Med. 1993 Mar;14(1):43-55



Fast forward…..

AI in biomedical applications



The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Jeffrey M. Drazen, M.D., *Editor;*
Isaac S. Kohane, M.D., Ph.D., and Tze-Yun Leong, Ph.D., *Guest Editors*

AI IN MEDICINE

Artificial Intelligence and Machine Learning in Clinical Medicine, 2023

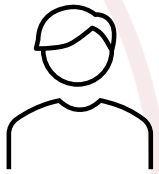
Charlotte J. Haug, M.D., Ph.D., and Jeffrey M. Drazen, M.D.

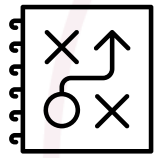
CONCLUSIONS

We firmly believe that the introduction of AI and machine learning in medicine has helped health professionals improve the quality of care that they can deliver and has the promise to improve it even more in the near future and beyond. Just as computer acquisition of radiographic images did away with the x-ray file room and lost images, AI and machine learning can transform medicine. Health professionals will figure out how to work with AI and machine learning as we grow along with the technology. AI and machine learning will not put health professionals out of business; rather, they will make it possible for health professionals to do their jobs better and leave time for the human–human interactions that make medicine the rewarding profession we all value.

Haug CJ, Drazen JM. Artificial Intelligence and Machine Learning in Clinical Medicine, 2023. N Engl J Med. 2023 Mar 30;388(13):1201-1208. doi: 10.1056/NEJMra2302038. PMID: 36988595.

AI in Healthcare is for Clinical Decision Support





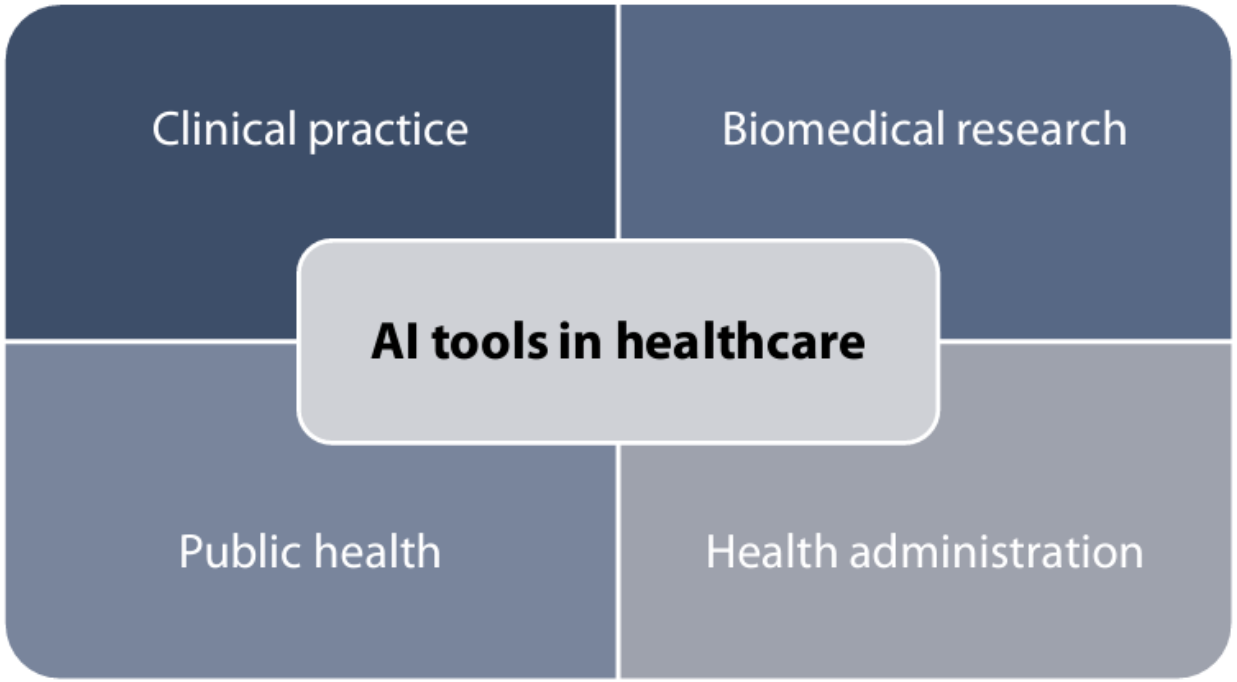
Clinical Decision Support System (CDSS):
A (software) tool that helps users take (complex) decisions

AI systems in healthcare

European Parliament

Artificial intelligence in healthcare

Applications, risks, and ethical and societal impacts



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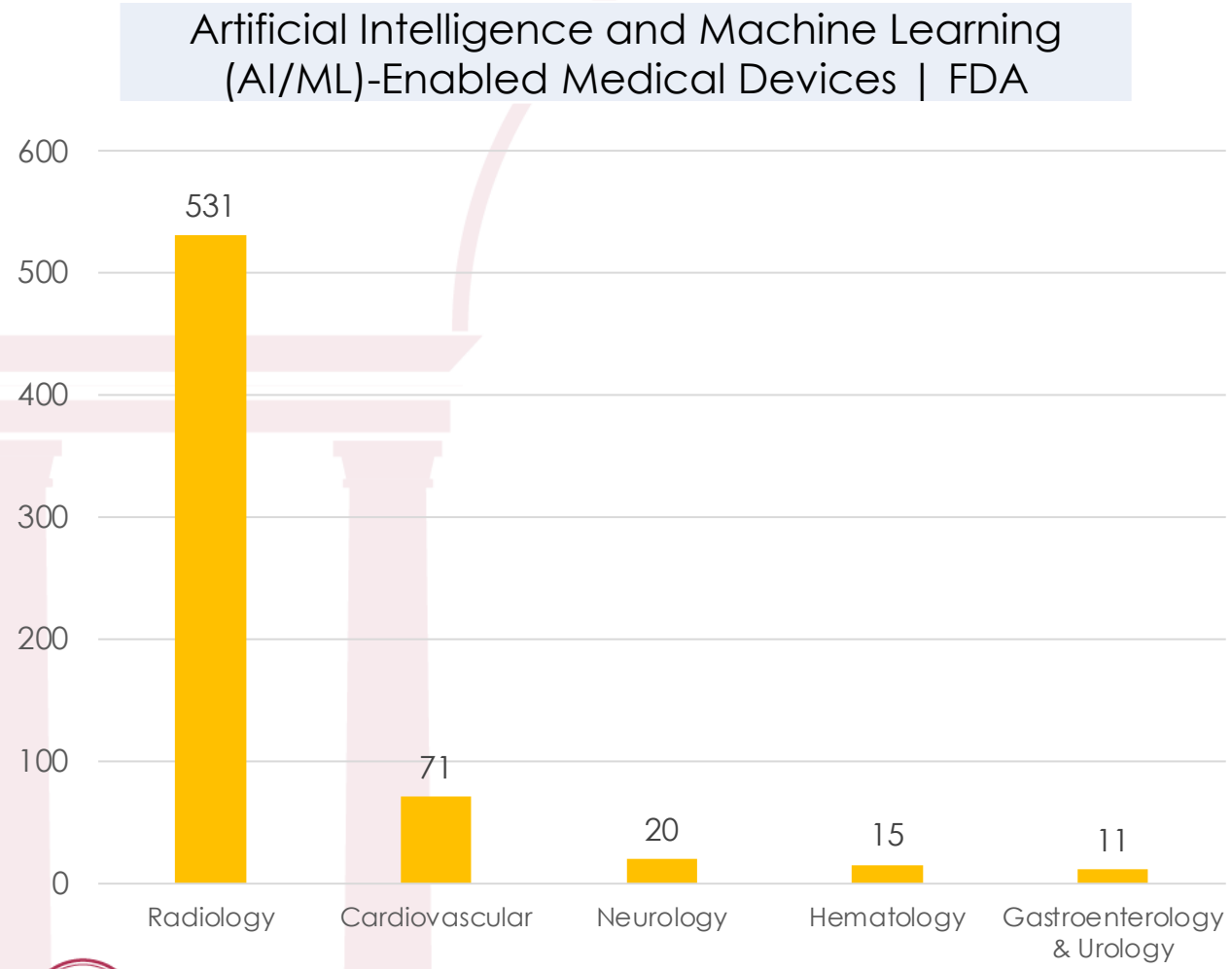
STUDY
Panel for the Future of Science and Technology

EPRS | European Parliamentary Research Service
Scientific Foresight Unit (STOA)
PE 729.512 – June 2022

EN

What is already translated to clinical practice?



Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices

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October 19, 2023 update: 171 Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices were added to the list below. Of those newly added to the list, 155 are devices with final decision dates between August 1, 2022, and July 30, 2023, and 16 are devices from prior periods identified through a refinement of methods used to generate this list.

Based on projected volume in 2023, the increase of AI/ML-enabled devices (compared to 2022) is expected to reach 30+%.

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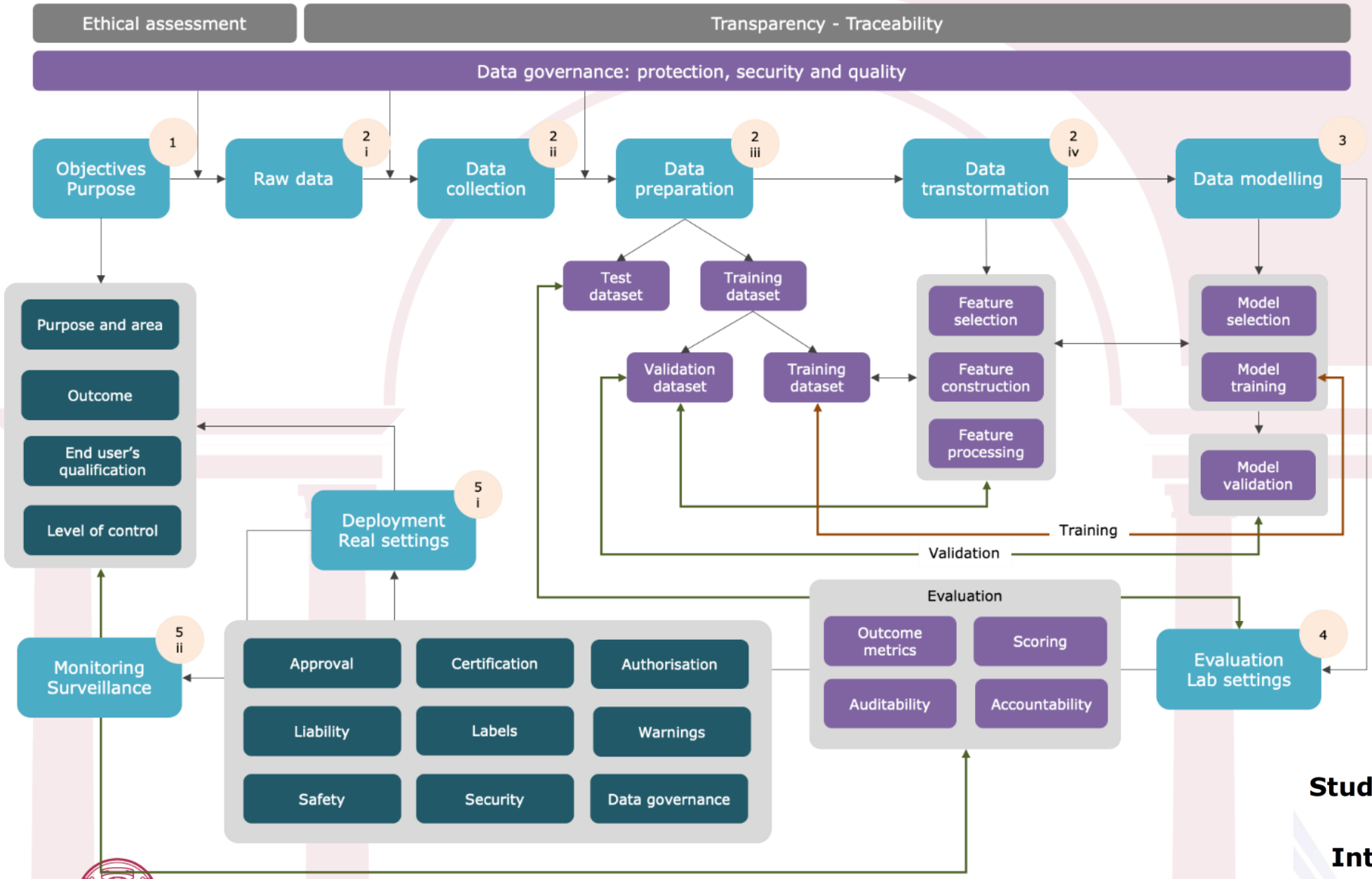
https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices



European Commission

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Study on Health Data, Digital Health and Artificial Intelligence in Healthcare

Figure 5. AI system phases in health

Deploying AI-based systems in healthcare is challenging

- Building Trust
- Addressing Data Bias and Interpretability
- Data governance
  - Data Privacy and Security
  - Data Quality
- Clinical Workflow Integration
- Compliance with Regulation and Standards

Ethics and Regulatory Challenges are strictly connected

AI systems are (often) classified as medical devices
AI systems are intended to be used on humans (patients)
AI systems process personal data related to health
AI systems use AI

Deploying AI-based systems in healthcare requires risk assessment

CHALLENGES

- Building Trust
- Addressing Data Bias and Interpretability
- Data governance
  - Data Privacy and Security
  - Data Quality
- Clinical Workflow Integration
- Compliance with Regulation and Standards

RISKS

Unauthorized access to personal data

Hazards related to malfunctioning of the system, including AI components

Incidental findings

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The NEW ENGLAND JOURNAL of MEDICINE

HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Understanding Liability Risk from Using Health Care Artificial Intelligence Tools

Michelle M. Mello, J.D., Ph.D., and Neel Guha, M.S.

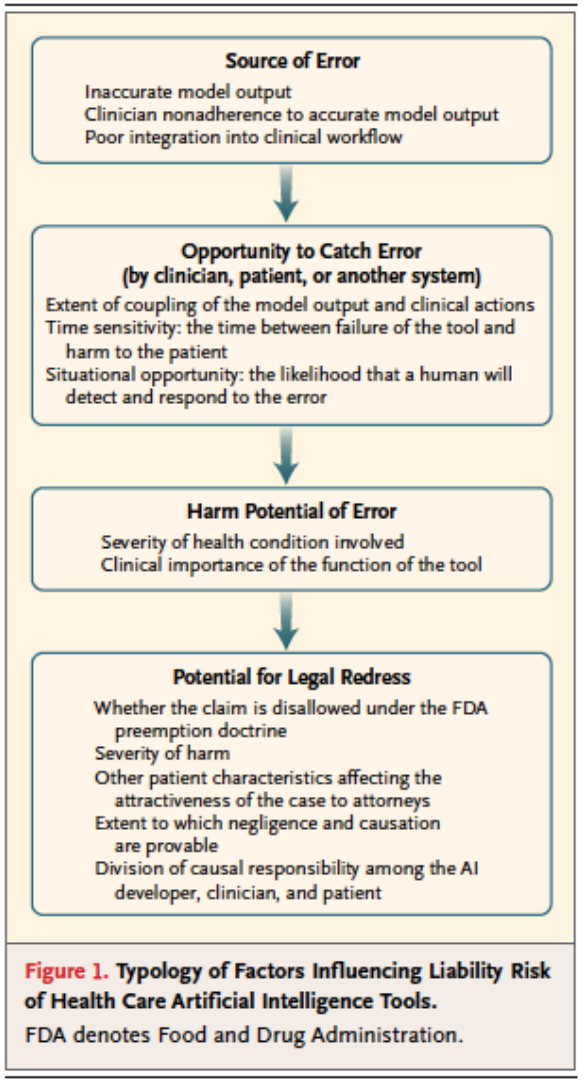

Figure 1. Typology of Factors Influencing Liability Risk of Health Care Artificial Intelligence Tools.

FDA denotes Food and Drug Administration.

An example: the CAPABLE project

EU Horizon 2020 Research and Innovation Programme (GA No 875052)
Coordinated by the University of Pavia, Italy
12 partners in Europe and Israel

AI-based decision support system for improving the quality of life of cancer home patients
Symptoms Monitoring and well-being interventions
Evidence-based recommendations to patients and HCPs – computerized clinical practice guidelines

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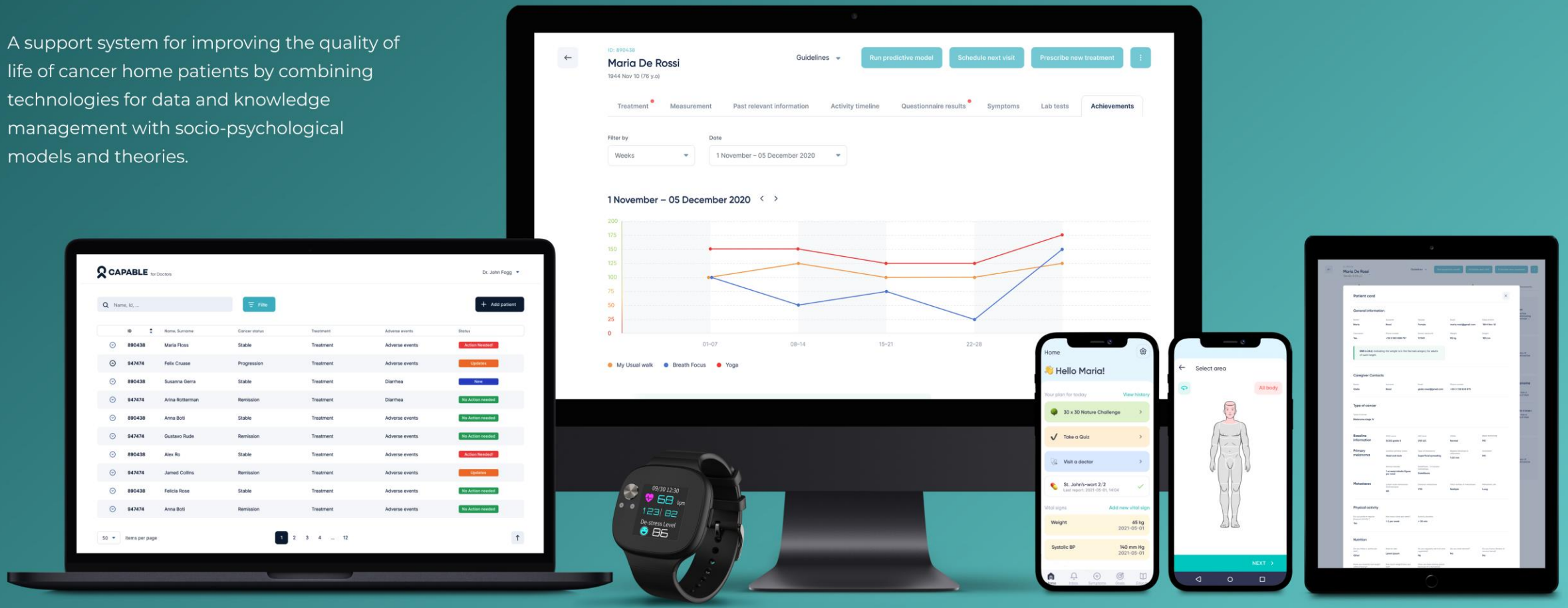
CAPABLE

CAncer PAtients Better Life Experience

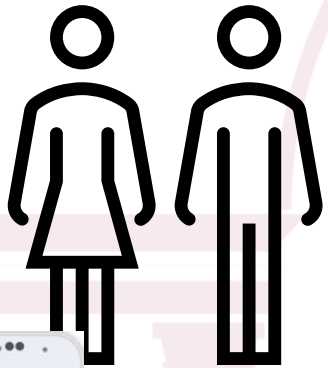
A support system for improving the quality of life of cancer home patients by combining technologies for data and knowledge management with socio-psychological models and theories.

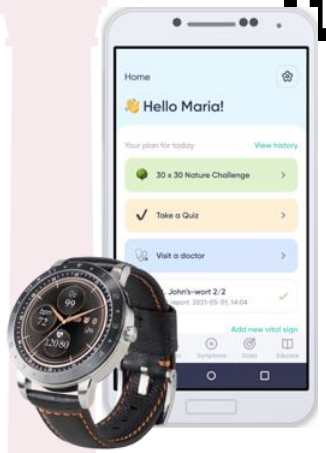


Bitsens · IBM · DEONTICS Clinical Futures · amc · Netherlands Cancer Institute · Politécnica · Istituti Clinici Scientifici Maugeri · University of Haifa · aimac associazione italiana malati di cancro, parenti e amici · BIOMERIS

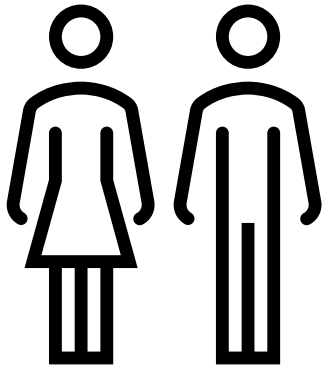
The CAPABLE pilot studies

Prospectively enrolling, quasi-experimental cohort studies in cancer patients, eligible for systemic treatment





CAPABLE cohort
receives the CAPABLE smartphone application and a smartwatch (ASUS VivoWatch) throughout treatment



CONTROL cohort
same features, but receiving standard care

Clinical sites

IT NL

Main study endpoint:
difference in the quality of life between the two populations, measured with the EORTC QLQ-C30 questionnaire

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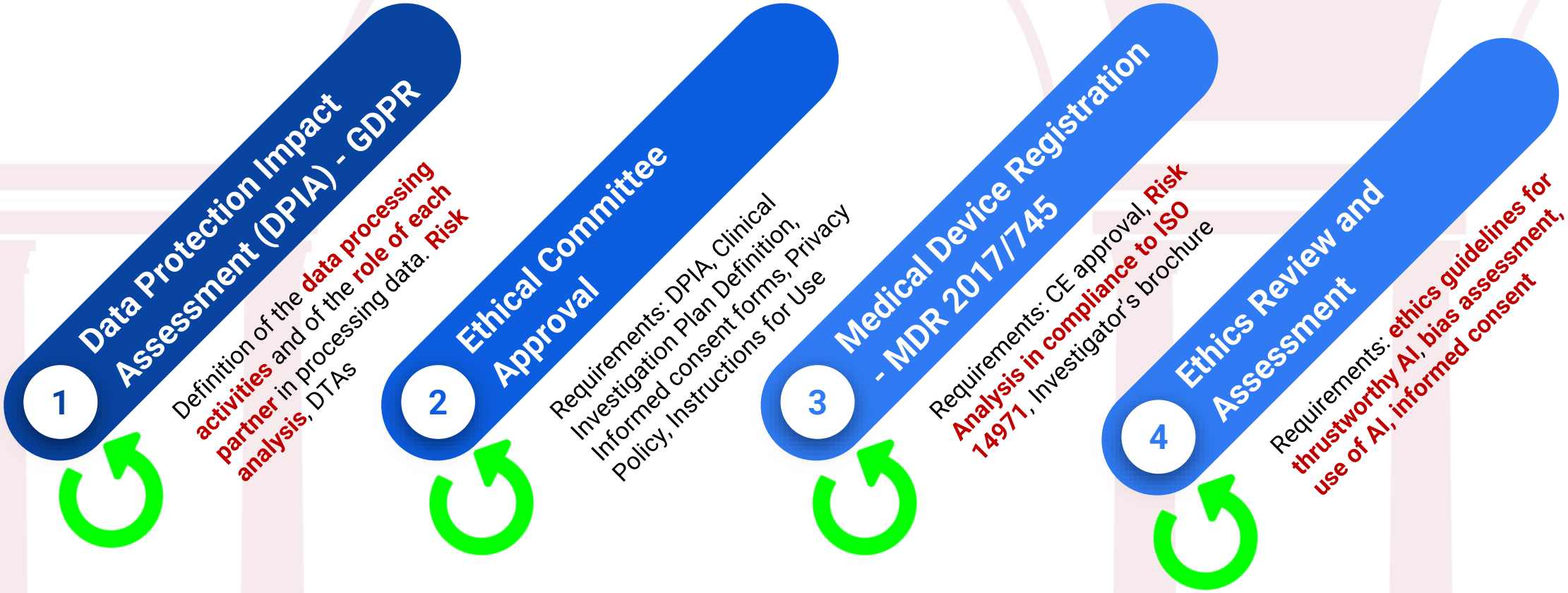
The Ethics/Regulatory Roadmap to the CAPABLE study



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September 2021 – August 2023

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