Responsible Machine Learning in Health: Regulatory and Legal Aspects

Invited workshop on "Responsible machine learning for healthcare"

26-27 October 2022

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Who am I?

- Pharmacist (2016)
- PhD in regulatory science (2021)
- Received an EliteResearch Travel Grant 2020 from the Danish Ministry of Higher Education and Science
- Invited young scientist to Lindau Nobel Laureate Meeting 2020.
- Since then, PostDoc at CeBIL at the Faculty of Law
  - Biologics project as part of the CeBIL collaborative research centre, supported by the Novo Nordisk Foundation (grant NNF17SA0027784).
  - Now: CLASSICA project on AI assisted surgery

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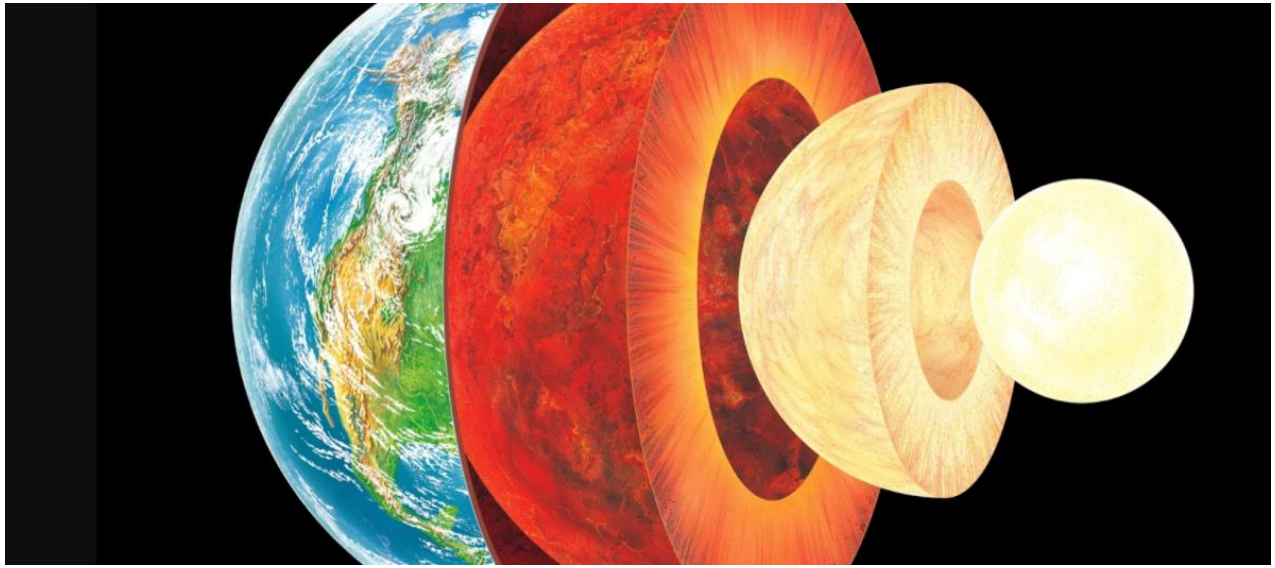
Michigan Law
University of Michigan Law School

AI, Machine Learning & Evolving Regulations

https://innovationatwork.ieee.org/ten-ways-ai-regulations-and-standards-will-evolve-in-2022/

https://www.medicaldesignandoutsourcing.com/fda-wants-public-input-on-ai-enabled-device-regulation/

‘Zoom out’ for regulatory and legal aspects

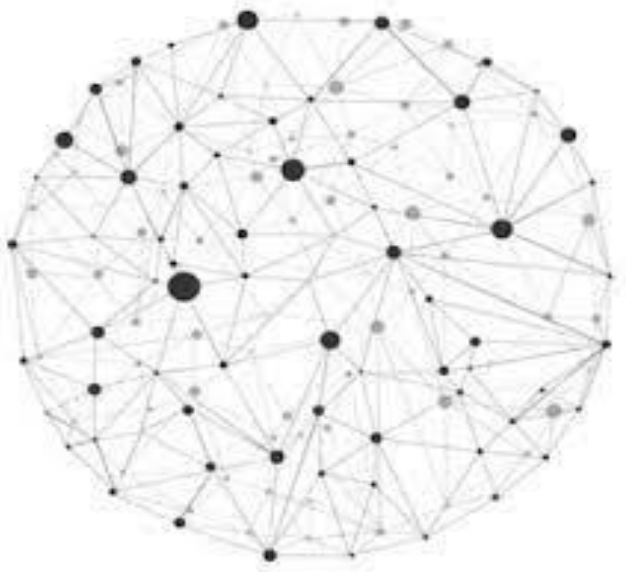


https://myannalahsen.com/science-policy/

Emerging super-complex regulatory ecosystem in Europe

- **Medical Device Regulation (MDR)**
- **EU AI Act (AI Regulation)**
- European Health Data Space (EHDS)
- General Data Protection Regulation (GDPR)
- EU Data Governance Act
- Digital Services Act (DSA)
- Digital Markets Act (DMA)
- European Open Science Cloud (EOSC)
- Evolving EU liability regimes

- Just to name a few.....



https://www.orthoservice.com/en/news/106/notice-to-resellers-new-medical-devices-regulation-mdr-2017745

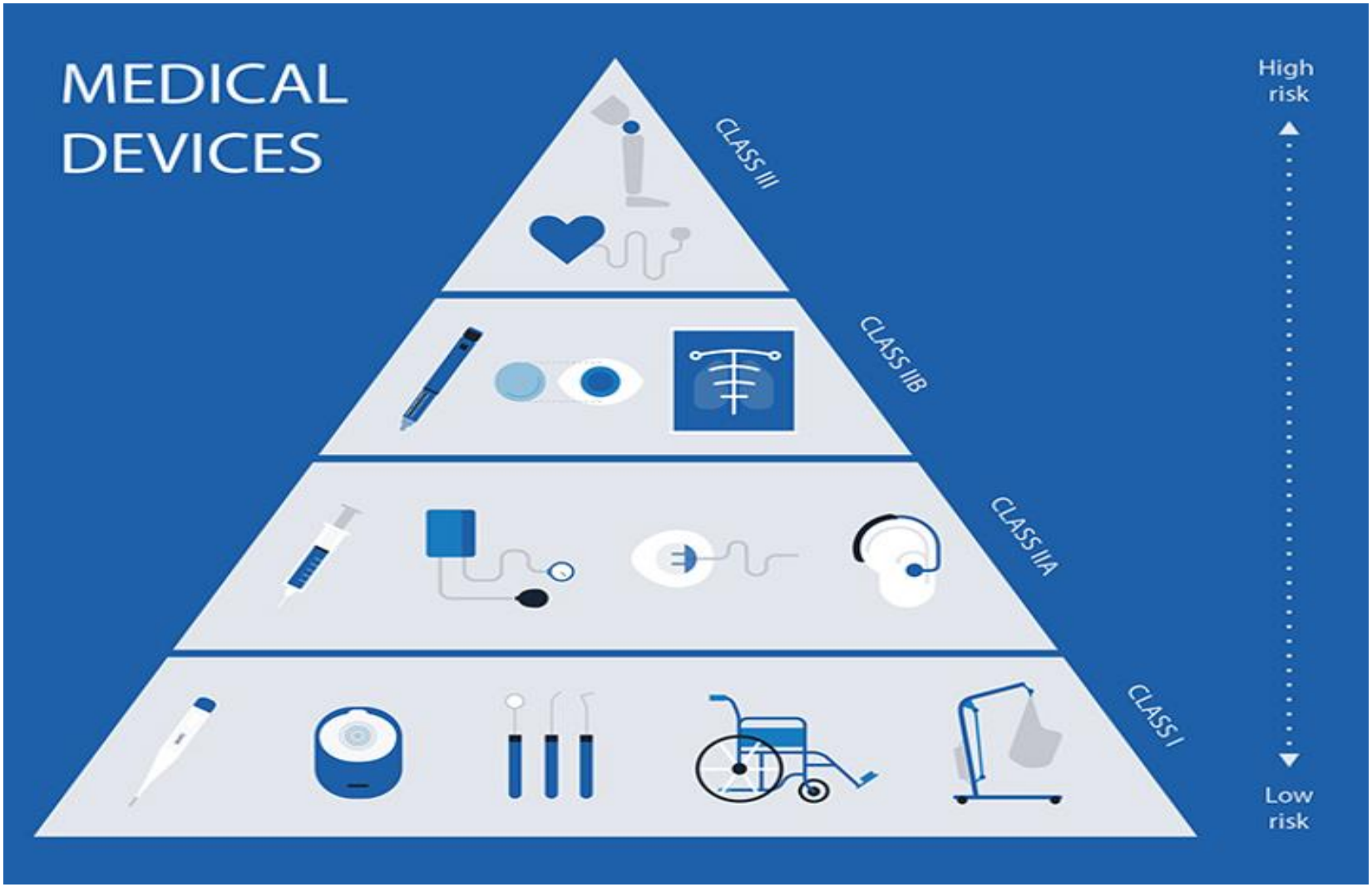
Definition of the term "medical device":

The new MDR defines the term "medical device" broadly as

- "any instrument, apparatus, appliance, **software,** implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: –

- diagnosis, prevention, monitoring, **prediction, prognosis,** treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, (⋯)

- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means" (MDR, Art. 2(1)).


MEDICAL DEVICES
CLASS III
CLASS IIB
CLASS IIA
CLASS I
High risk
Low risk

Software as a medical device under the MDR

- Software intended to **provide information which is used to take decisions with diagnosis or therapeutic purposes** is classified as **class IIa,**

- **except** if such decisions have an impact that may cause: — **death or an irreversible deterioration of a person's state of health**, in which case it is in **class III;**

- or, — a **serious deterioration** of a person's state of health or a surgical intervention, in which case it is classified as **class IIb.**

- "software intended to **monitor physiological processes** is classified as **class IIa**" **only in cases <u>where it is not</u> "intended for monitoring of vital physiological parameters**, where the nature of variations of those parameters is such that it could result in immediate danger to the patient" (**class II b**) (Rule 11 in Chapter III of Annex VIII)39,40.

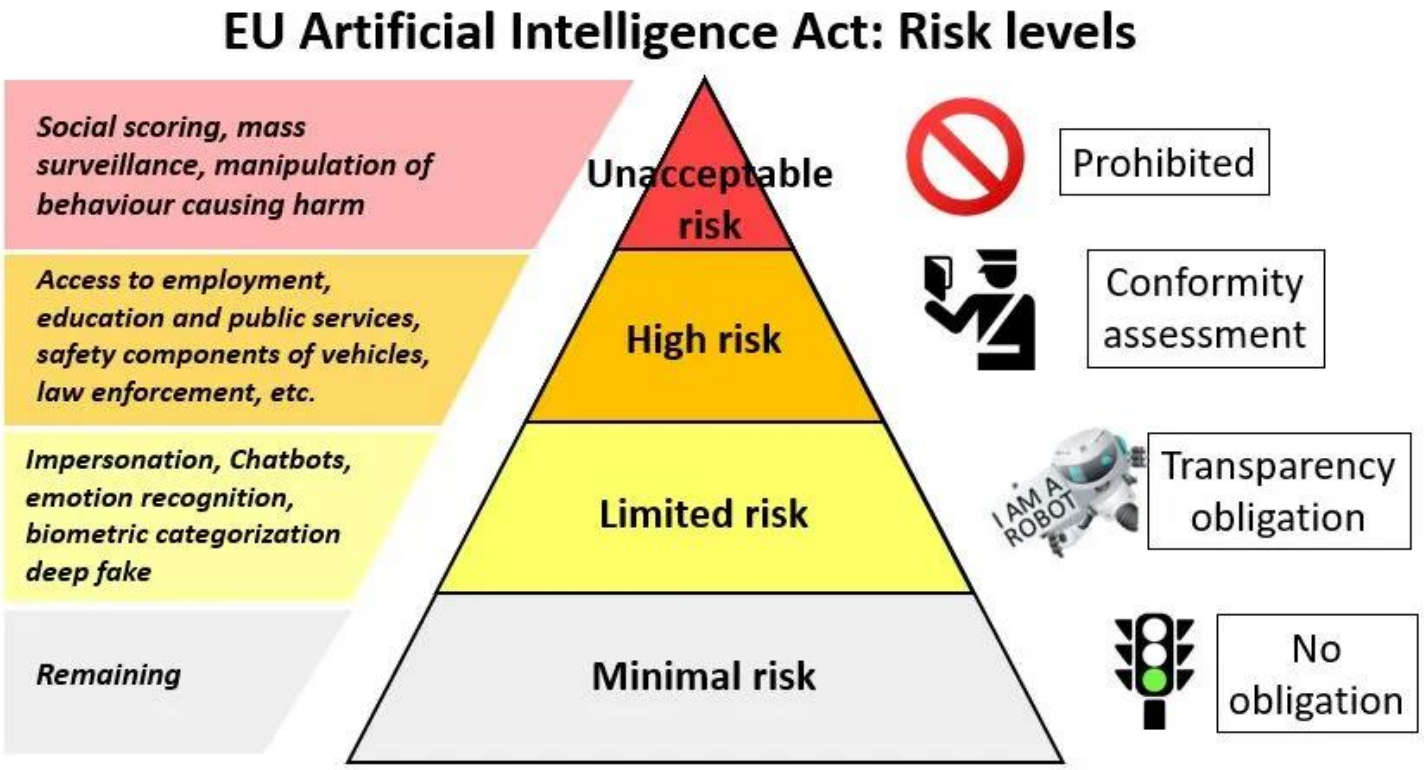
Intellisoft

Key changes of the new MDR

https://intellisoft.io/understanding-the-new-rules-the-mdd-vs-mdr/

The emerging EU AI Regulation / AI Act

AI act and risks:



https://www.telefonica.com/en/communication-room/blog/a-fit-for-purpose-and-borderless-european-artificial-intelligence-regulation/

Selected challenges linked to regulating AI and Machine Learning

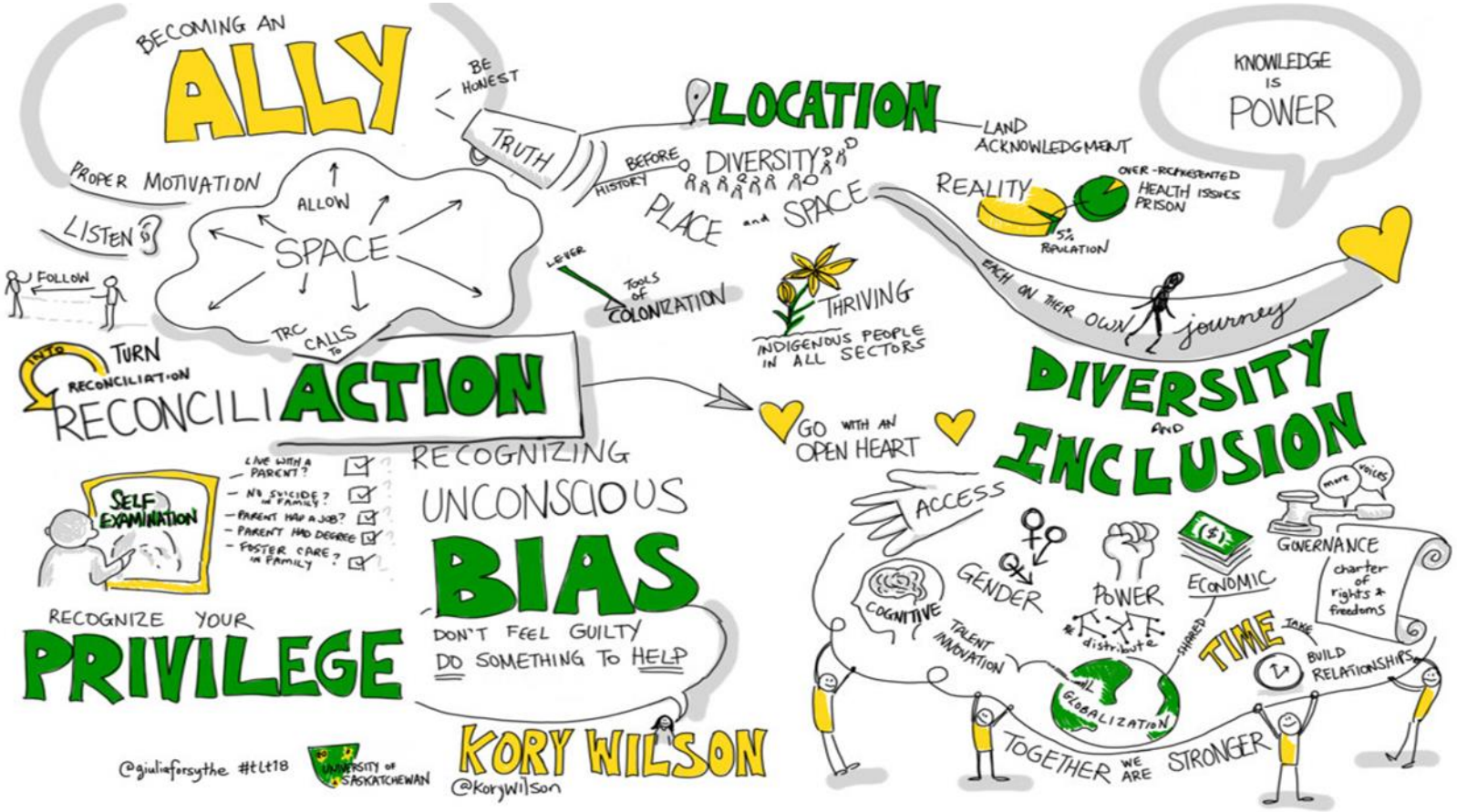
Data Privacy, Exportation, Exploitation, and Equitable Access

https://www.med-technews.com/medtech-insights/medtech-regulatory-insights/what-medical-devices-and-processes-pose-a-risk-to-gdpr/

https://blog.chino.io/how-is-mdr-related-to-gdpr/

https://starfishmedical.com/blog/medical-devices-gdpr-eu-general-data-protection-regulation/

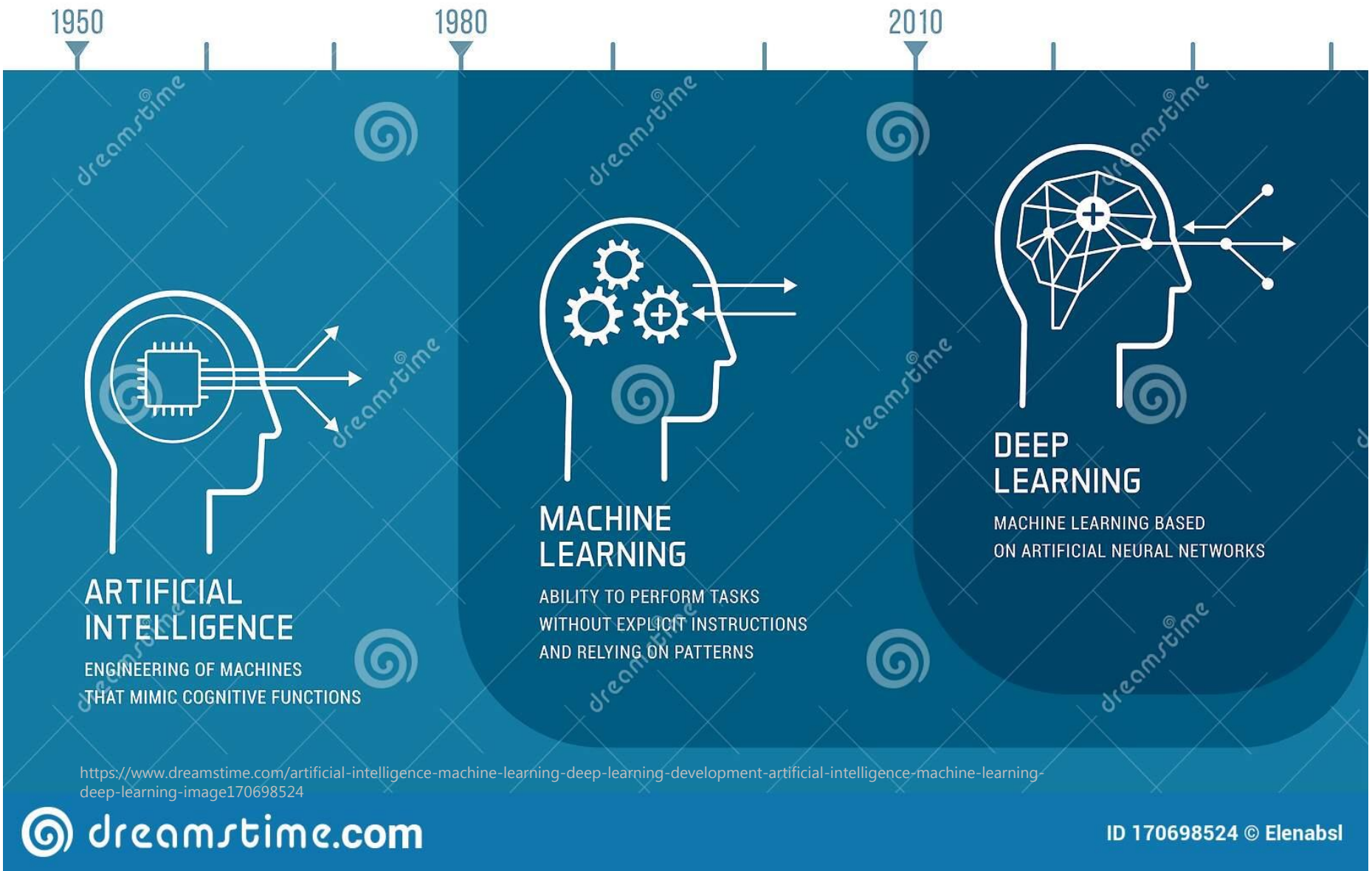
Training Set Bias, Contextual Bias, and Trade Secrecy



A crucial distinction of AI systems for law and regulation

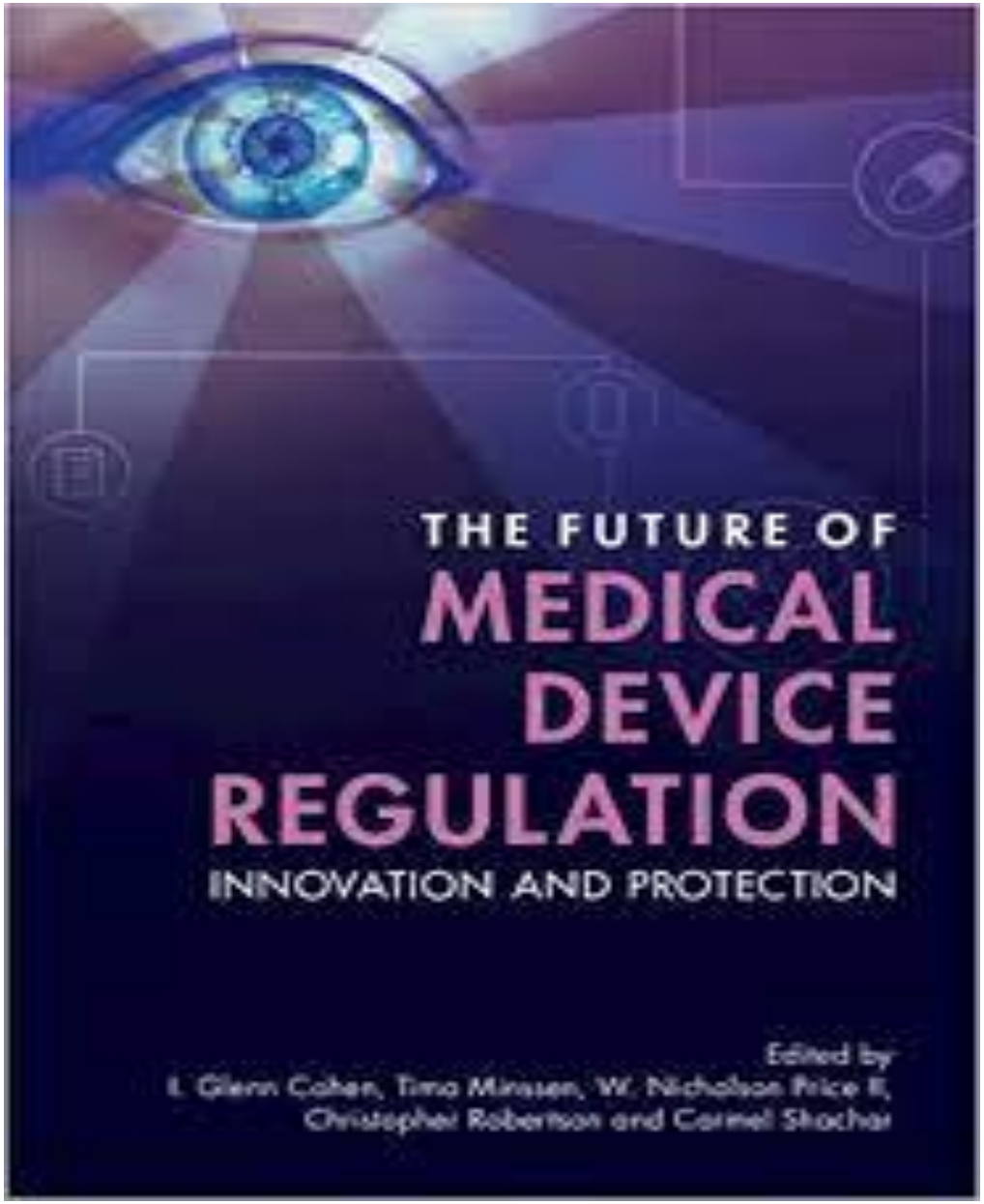
Locked vs. adaptive algorithms

The "Update" problem



For further issues, check this out!

Cohen, I., Minssen, T., Price II, W., Robertson, C., & Shachar, C. (Eds.). (2022). The Future of Medical Device Regulation: Innovation and Protection. Cambridge: Cambridge University Press. doi:10.1017/9781108975452



“Soft” (but nevertheless important) regulation and new crucial guidance

Photo by Darth Liu on Unsplash

"Ethics and governance of artificial intelligence for health"

World Health Organization

The six key principles

1. **Protecting human autonomy**
2. **Promoting human well-being, safety & the public interest**
3. **Ensuring transparency, explainability and intelligibility**
4. **Fostering responsibility and accountability**
5. **Ensuring inclusiveness and equity**
6. **Promoting AI that is responsive and sustainable.**

Source: https://www.picpedia.org/keyboard/images/principles.jpg

The CLASSICA Project

https://jura.ku.dk/cebil/research/classica/

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  - JURFAST - The Legal Framework for the use of health data

CeBIL > Research > CLASSICA - Regulatory ...

CLASSICA - Regulatory and legal aspects of an AI-based medical device

CLASSICA is an EU-Horizon-funded project that evaluates an AI-based clinical decision support tool for cancer surgeons through clinical validation as well as investigation of regulatory and legal aspects.

Colorectal cancer is the third most common cancer type globally and the second most common cause of cancer death, leading to almost one million deaths annually. CLASSICA builds on breakthrough research in AI analysis that allows excellent detection of cancerous tissue. In CLASSICA, we transform a research prototype for such detection of colorectal cancer into a real-time

Funding

Funded by the European Union

CLASSICA is a 4-year project supported by EU-Horizon funds.

Project: Validating AI in Classifying Cancer in Real-Time Surgery (Grant 101057321)

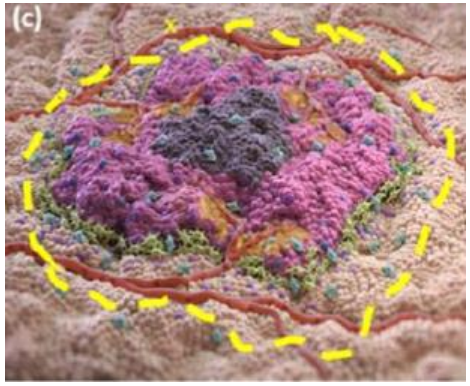
Period: 2022-2026

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

Objective of CLASSICA project

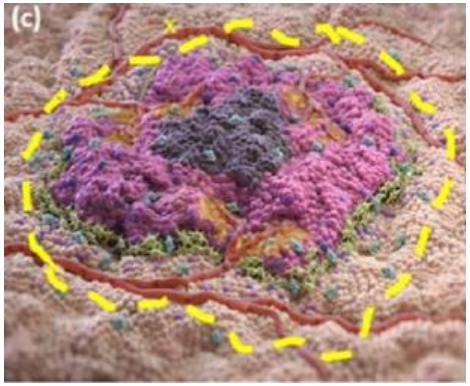
- The objective of project CLASSICA is to clinically validate a novel AI-guided intraoperative decision support technology in the surgical care of cancer patients, across several clinics, surgical teams and countries.

- An AI-based algorithm is used to differentiate between cancerous and non-cancerous tissues in real time.



Artificial intelligence in CLASSICA

- Unlike 'deep-learning'-based AI systems, CLASSICA is a '**white box' AI** solution.
- The decision algorithms, the variables taken into account and the recommendations made for each individual can be viewed, analysed and explained to clinicians or patients whenever required.
- This 'transparent' nature of our AI removes sources of ethical uncertainty associated with 'black box' deep-learning-based AI.



Research parts of CLASSICA

1. Deploy the classification technique to five different clinical settings (Ireland, Belgium, Austria, Italy, and the Netherlands)
2. Carry out a clinical validation study in each setting
3. Assess usability, safety, and performance of CLASSICA in multiple settings
4. Create standard operating protocols for creation, interpretation, and use of CLASSICA information

(…)

8. Assessment of regulatory landscape, bias, and liability

Conclusions

- Perils to be addressed and mitigated on a global scale
- Opportunities and benefits to be harvested
- The current regulatory frameworks lag behind the use of MML = regulatory uncertainty with risks for manufacturers.
- MML manufacturers must spend substantial effort and resources to understand regulations in the particular context of MML devices.
- Legal frameworks evolving but super-complex

- Lots of work to do and much need for collaboration!

World Health Organization

Thank you! Comments?

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- Web: www.cebil.dk, https://jura.ku.dk/cebil/research/classica/
- News: http://jura.ku.dk/cebil/subscribe-to-news-from-cebil/

CLASSICA

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