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Helsinki, 20-22 September 2022

Source:	University of Copenhagen
Title:	Att.5 – Presentation - Regulatory responses to medical machine learning
Purpose:	Discussion
Contact:	Louise Druedahl E-mail: louise.druedahl@jur.ku.dk
Abstract:	This PPT contains a presentation from the workshop on AI for health on “Regulatory responses to medical machine learning”.

Regulatory responses to medical machine learning

ITU/WHO Workshop on "AI for Health"

Helsinki, 19 September 2022, 12-13.05 CET

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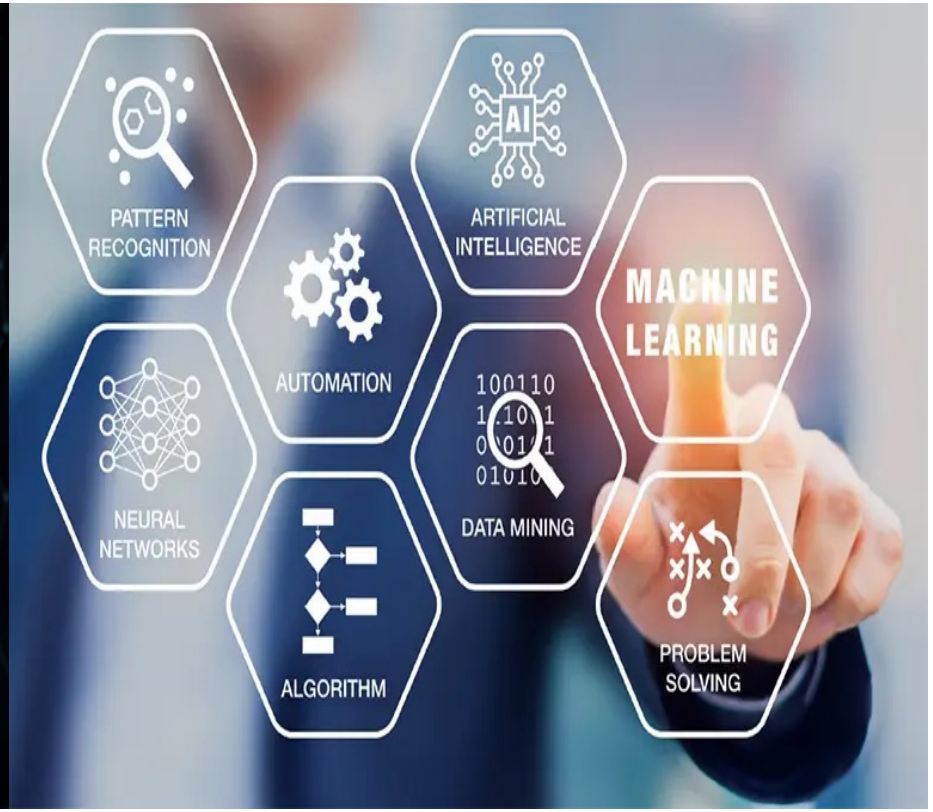
Centre for Advanced Studies in Biomedical Innovation Law (CeBIL), University of Copenhagen

AI, Machine Learning & Evolving Regulations

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

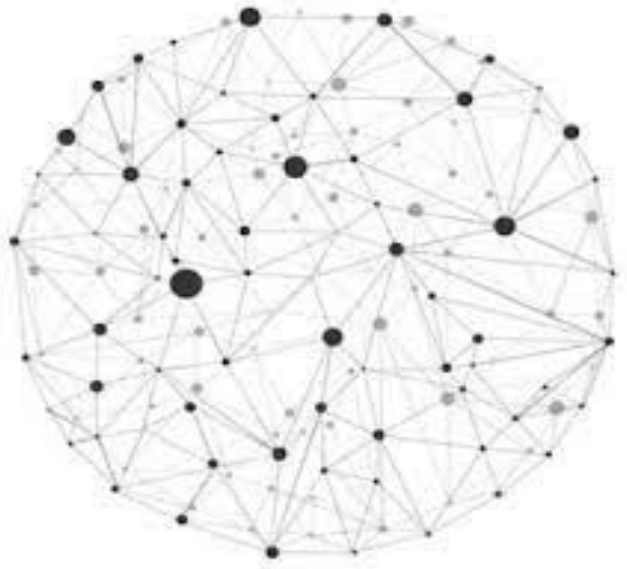


https://www.medicaldesignandoutsourcing.com/fda-wants-public-input-on-ai-enabled-device-regulation/

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

Key changes of the new MDR

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

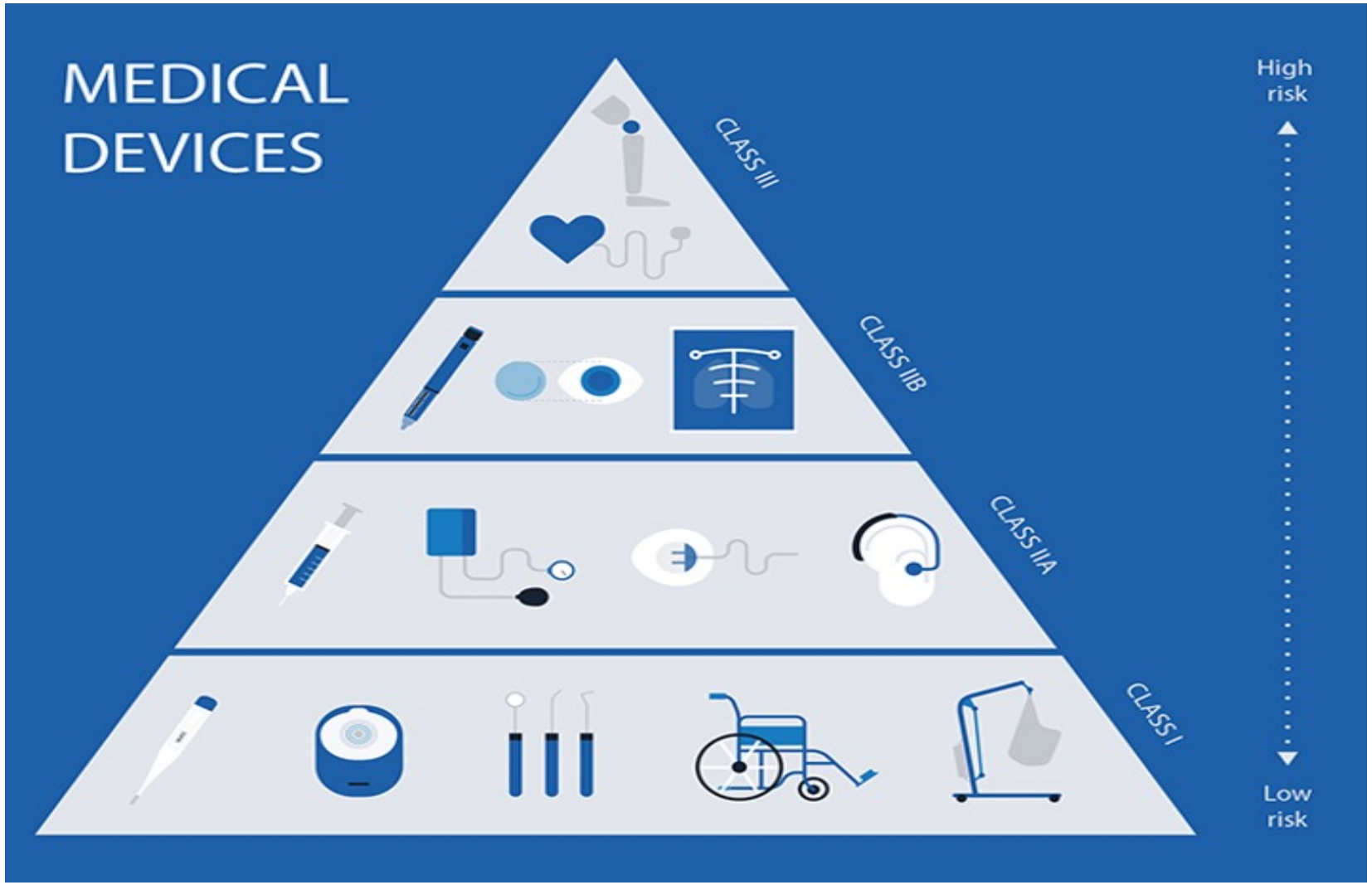
Definition of the term "medical device":

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,**

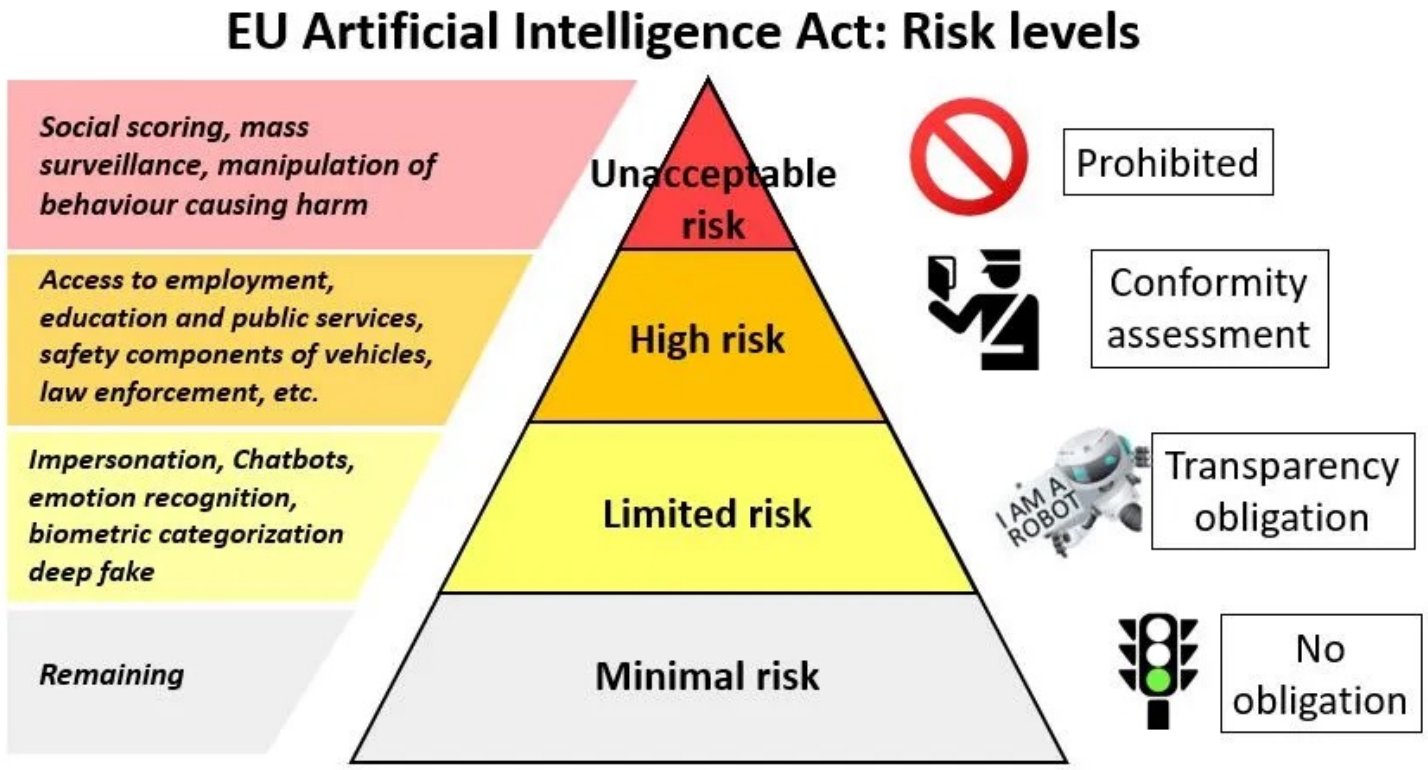
- **except** if such decisions have an impact that may cause: — **death or an irreversible deterioration of a person's state of health**, in which case it is in **class III;**

- 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.

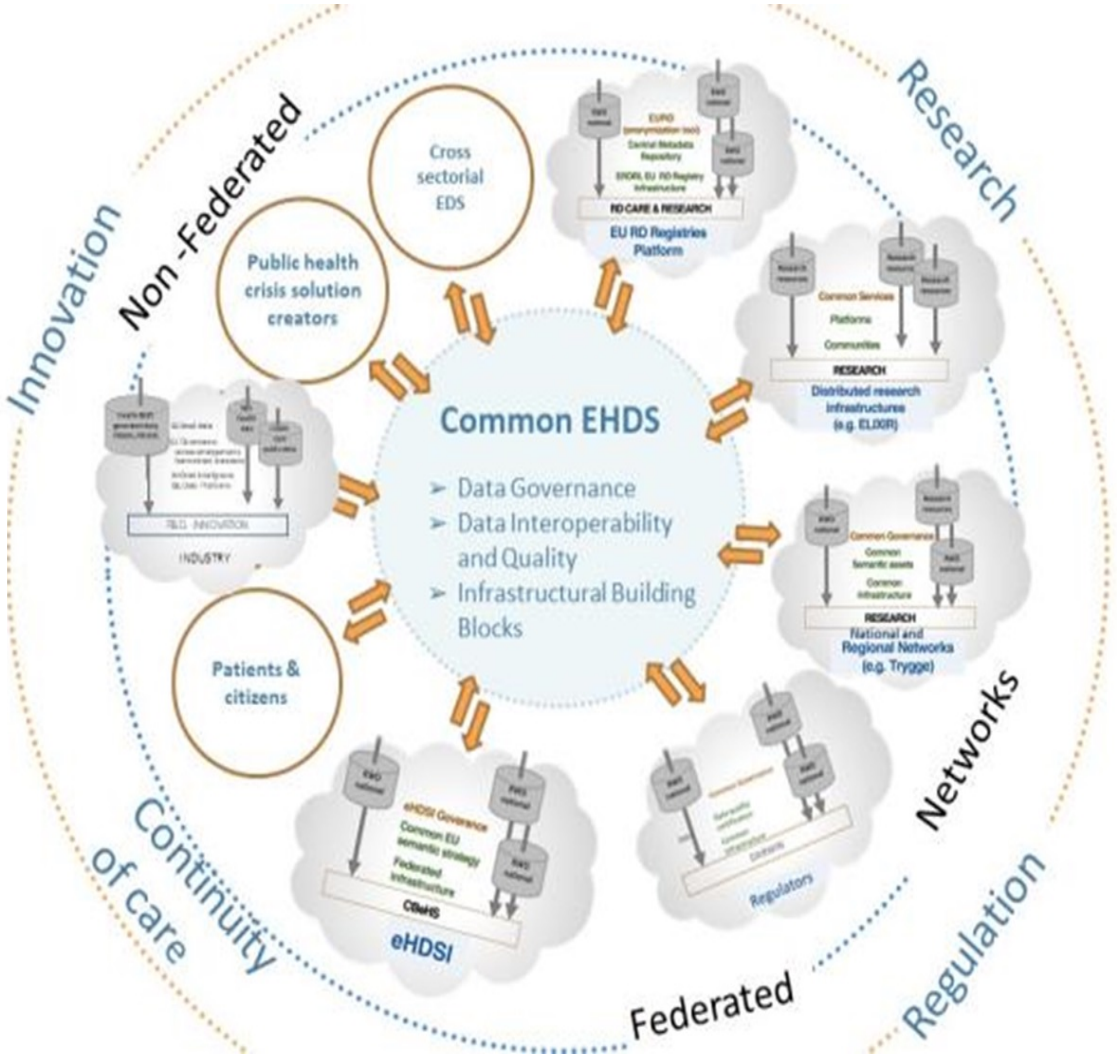
The emerging EU AI Regulation / AI Act

AI act and risks:



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

The European Health Data Space (EHDS) Act



https://errin.eu/news/errin-supports-digitalhealtheurope-recommendations-european-health-data-space

Selected challenges linked to regulating AI and Machine Learning

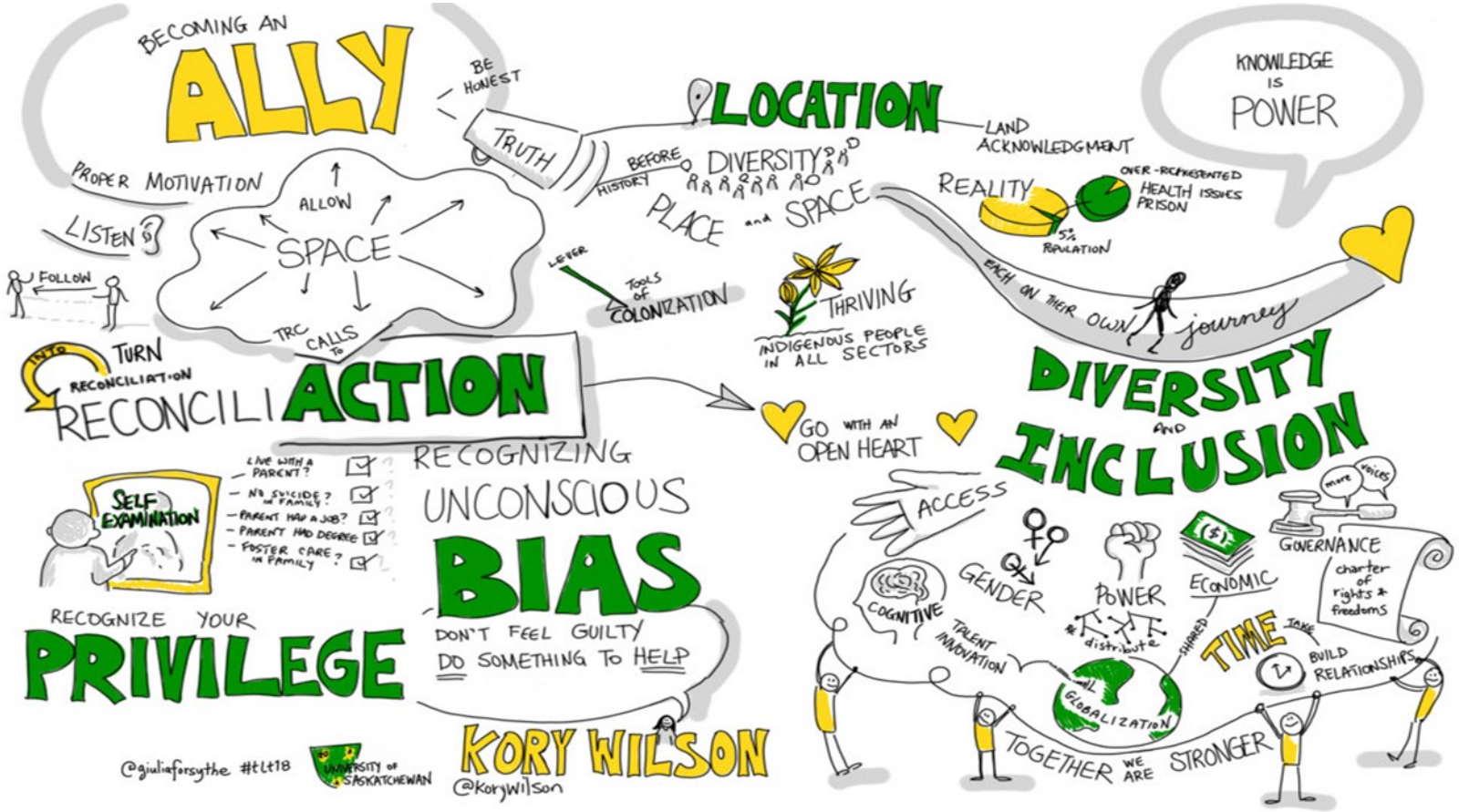
Data Privacy, Exportation, Exploitation, and Equitable Access

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

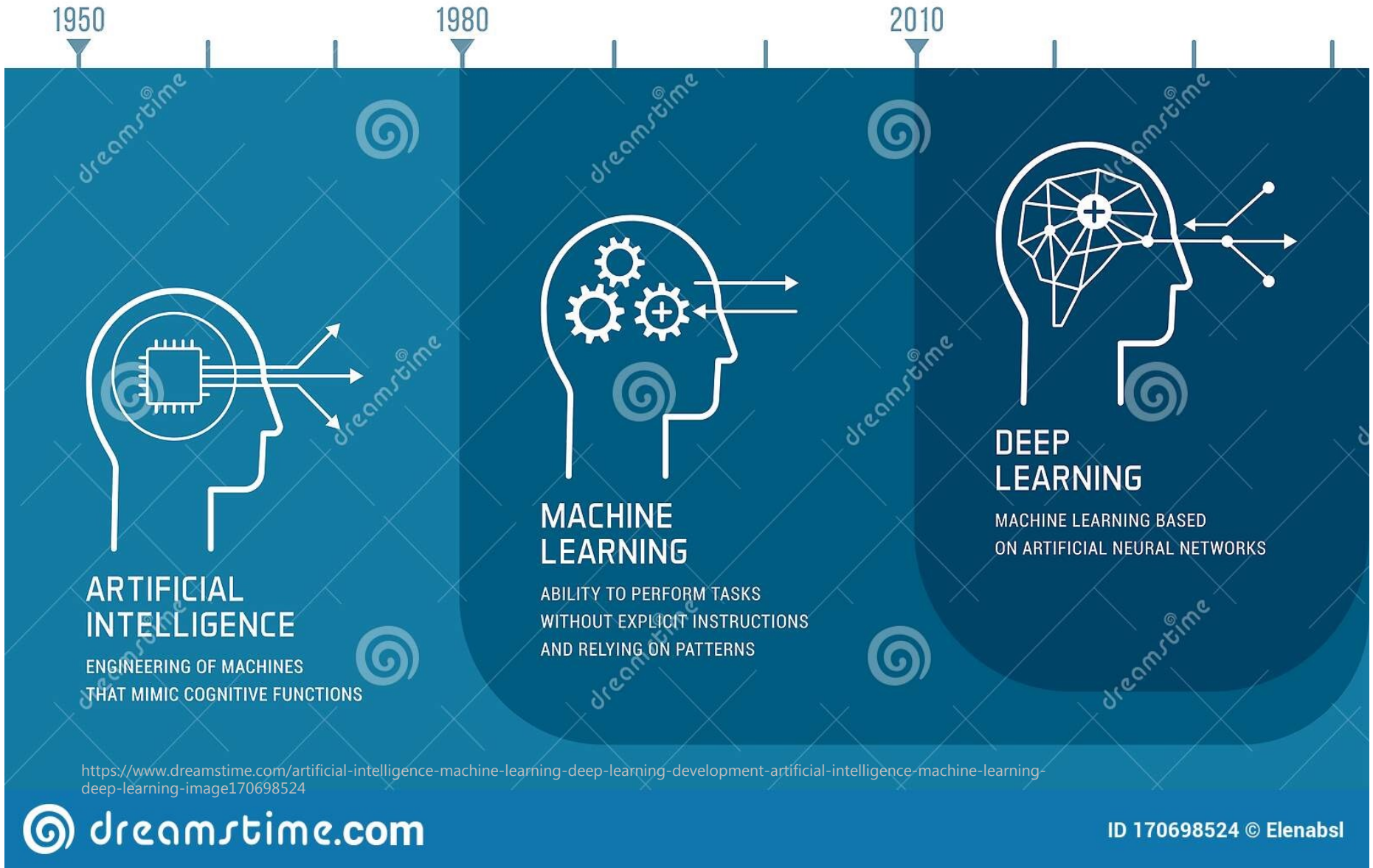
https://blog.chino.io/how-is-mdr-related-to-gdpr/

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

Training Set Bias, Contextual Bias, and Trade Secrecy

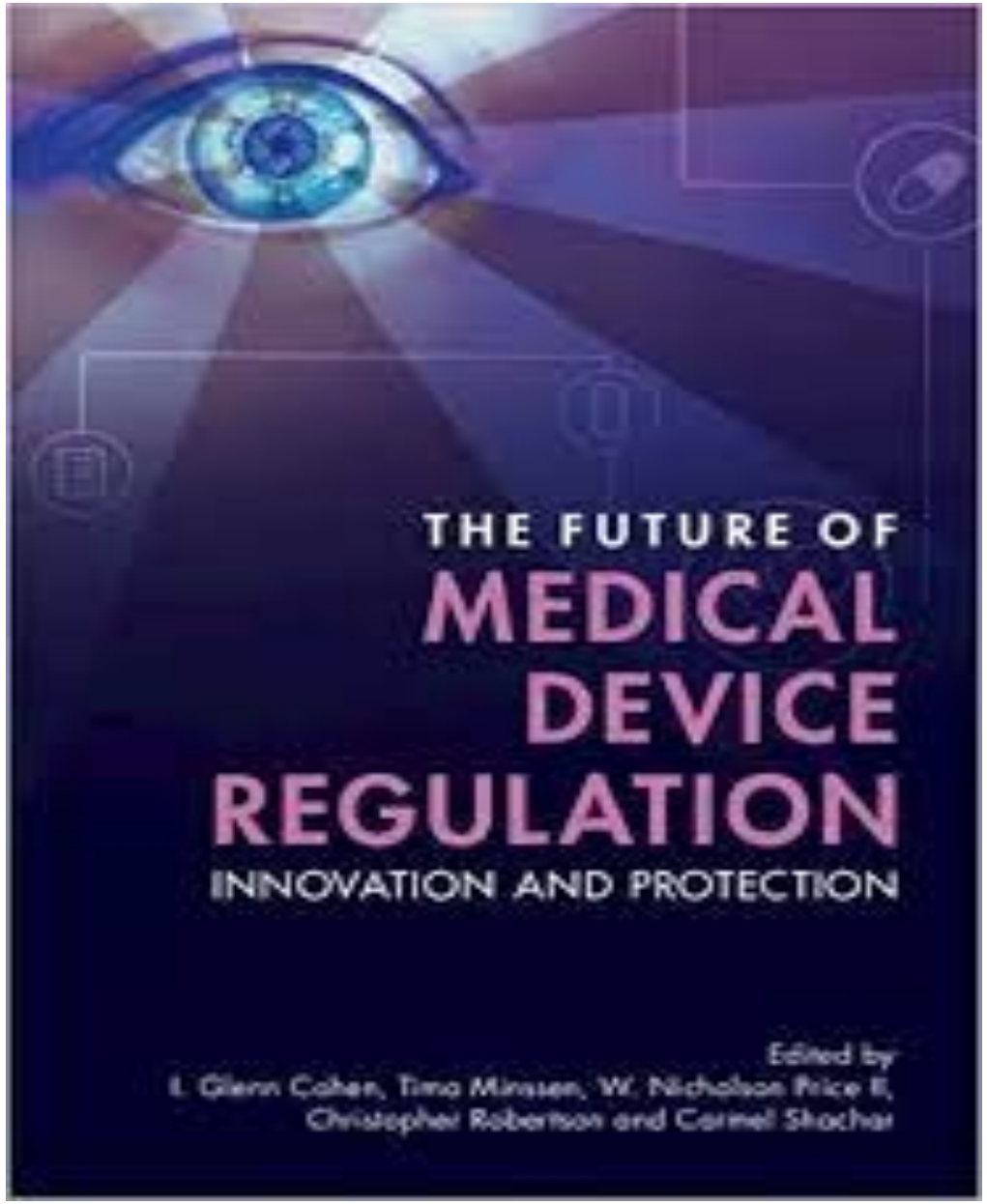


The "Update" problem



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"

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

CLASSICA - Regulatory and legal

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

CeBIL

- About CeBIL
- Staff
- Research
  - AI@Care: Law and Ethics and Algorithmic Bias in Healthcare
  - **CLASSICA - Regulatory and legal aspects of an AI-based medical device**
  - Collaborative Research Program in Biomedical Innovation Law
  - Global IPR and Life Sciences
  - Reconceptualising Reproductive Rights
  - Regulation of Patient Centered Clinical Trials (REPACT)
  - RESPOND3 - Responsible early Digital Drug Discovery
  - Technologies of Death and Dying at the Beginning of Life
  - Ice age - Entangled Lives, Times, and Ethics in Fertility Preservation
  - JURFAST - The Legal Framework for the use of

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

Funding

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.

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!

Thanks! Comments?

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