EPFL AMLD

LEGAL ASPECTS OF ARTIFICIAL INTELLIGENCE IN THE MEDICAL FIELD: AN OVERVIEW

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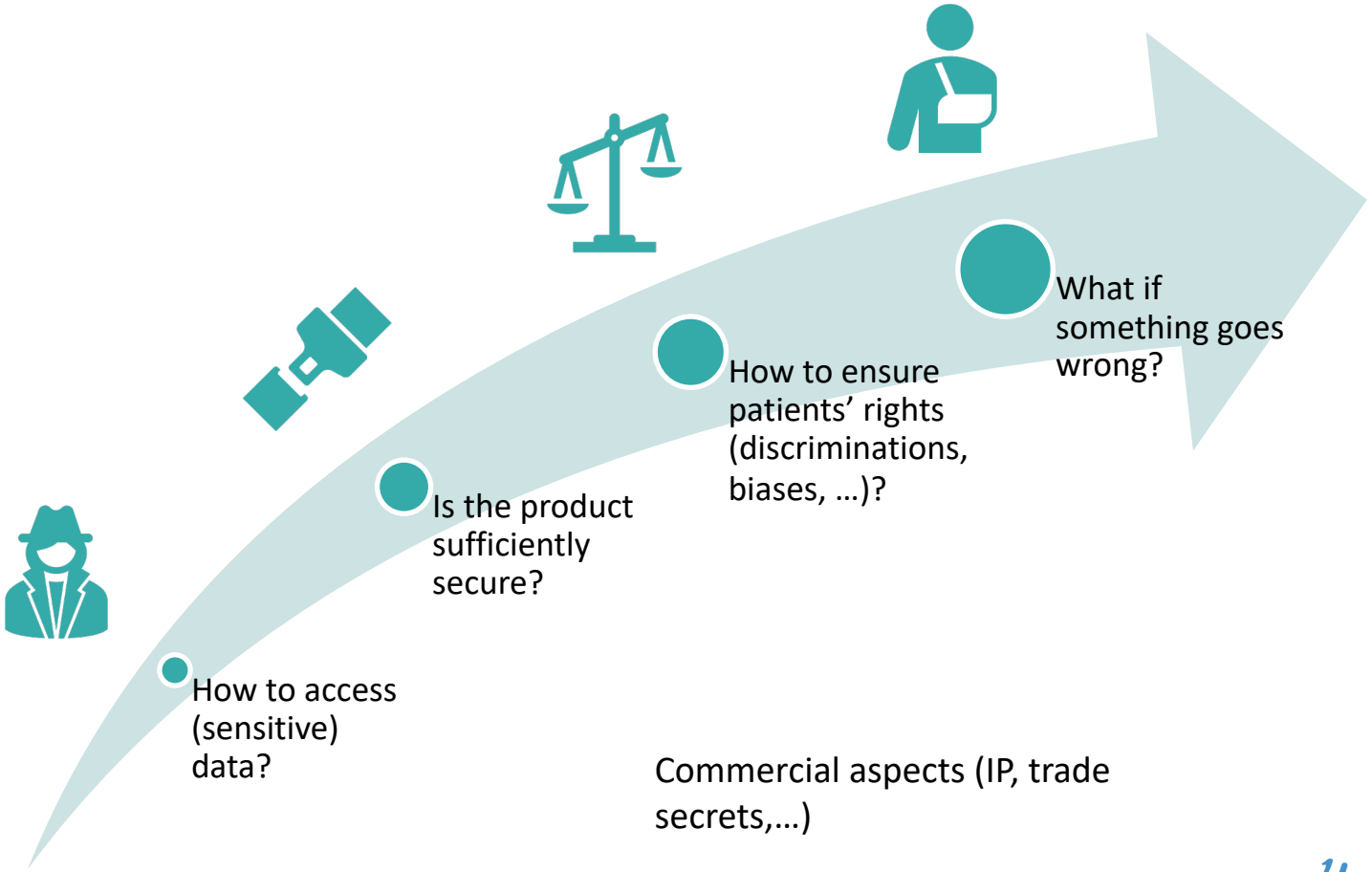
INTRODUCTION

Short overview of regulatory aspects for the development and implementation of clinical AI


How to access (sensitive) data?
Is the product sufficiently secure?
How to ensure patients' rights (discriminations, biases, …)?
What if something goes wrong?
Commercial aspects (IP, trade secrets,…)

PRIVACY

DATA

- Challenge: access to large amounts of personal/sensitive data
- Multiple data protection regulations (Swiss fDPA/cantonal laws, GDPR, national laws) / fragmented regulatory framework
- Health data is considered as sensitive data (special protection)

DATA

New challenges posed by clinical AI in relation to data access, e.g.:

- How to manage individual privacy rights ? E.g. access right, deletion/right to be forgotten

Technical solutions may help mitigate risks, e.g.:

- Trusted environments
- Pricacy enhancing technologies

EUROPEAN HEALTH DATA SPACE

European Commission - Press release

Commission welcomes political agreement on European Health Data Space

Brussels, 15 March 2024

The Commission welcomes the political agreement reached today between the European Parliament and the Council of the EU on the European Health Data Space (EHDS) - one of the **central building blocks of a strong European Health Union**. The rules proposed by the Commission in May 2022 have two main aims:

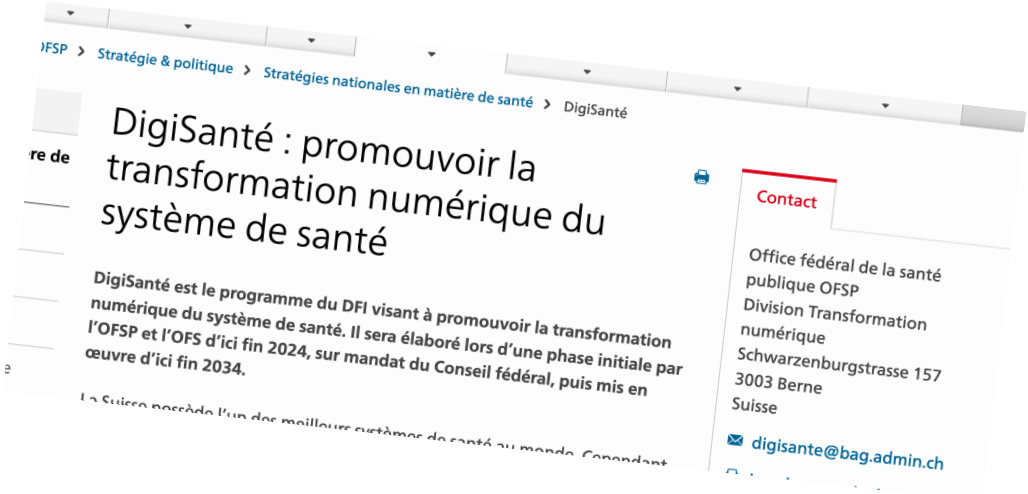
- To put citizens at the centre of healthcare, giving them full control over their data to obtain **better healthcare across the EU**;
- To open up data for **research and public health** uses.

Among the objectives:

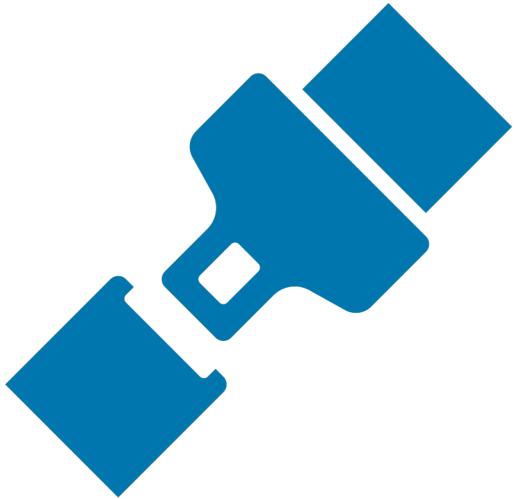
- secondary use of data across Europe, in particular for training, testing and evaluating algorithms
- most health data holders forced to make data available

DATA - SWITZERLAND

- Access to large sets of health data remains difficult, although progress has been made (e.g. SPHN)
- Creation of a Swiss health data space via the Digisanté initiative (next 10 years)?



SAFETY



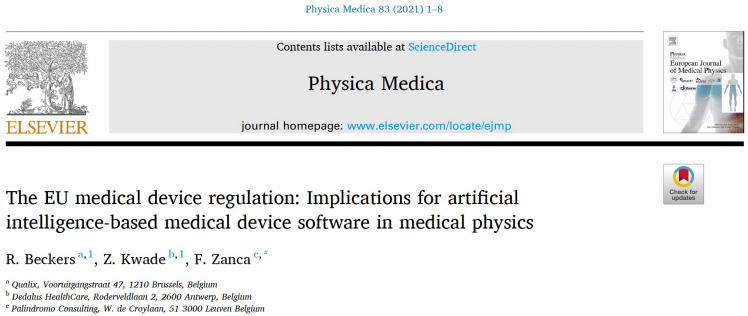
SAFETY

- Medical device regulations
  - EU: MDR, IVDR
  - CH: Therapeutic Products Act, Medical Devices Ordinance, IvDO
- Scope: **device intended to be used for specific medical purposes**

SAFETY

- AI medical software devices will in principle be classified in class IIa or superior (MDR Annex VIII Section 6.3, Rule 11)
- Conformity assessment and certification by a private notified body (CE marking) for classes IIa or superior
- Lighter conditions for in house development/use

SAFETY



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The EU medical device regulation: Implications for artificial intelligence-based medical device software in medical physics

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MDR Roadmap

1. Identification of requirements (**qualification**, **classification**, commercial strategy)
2. Design and development (General Safety and Performance Requirements, risk management, clinical evidence...)
3. Regulatory submission (declaration of conformity, conformity assessment)
4. Post-Market Surveillance

Quality Management Sytem

AI SPECIFIC (FUNDAMENTAL RIGHTS, SAFETY, INNOVATION)

FUNDAMENTAL RIGHTS/SAFETY

AI poses new risks, e.g. fundamental rights, security, democracy, environment

EU adopted a binding regulation to ensure both trustworthy AI and innovation

- AI Act (wide scope but not scientific research)

Switzerland has not yet planned/adopted similar regulations (under evaluation)

Impact of EU AI Act in Switzerland (extraterritorial effect if ouput of AI is used in the EU; access to EU market)

TECH

World's first major act to regulate AI passed by European lawmakers

PUBLISHED WED, MAR 13 2024•7:31 AM EDT | UPDATED WED, MAR 13 2024•12:14 PM EDT

Karen Gilchrist @_KARENGILCHRIST | Ruxandra Iordache @RMIORDACHE

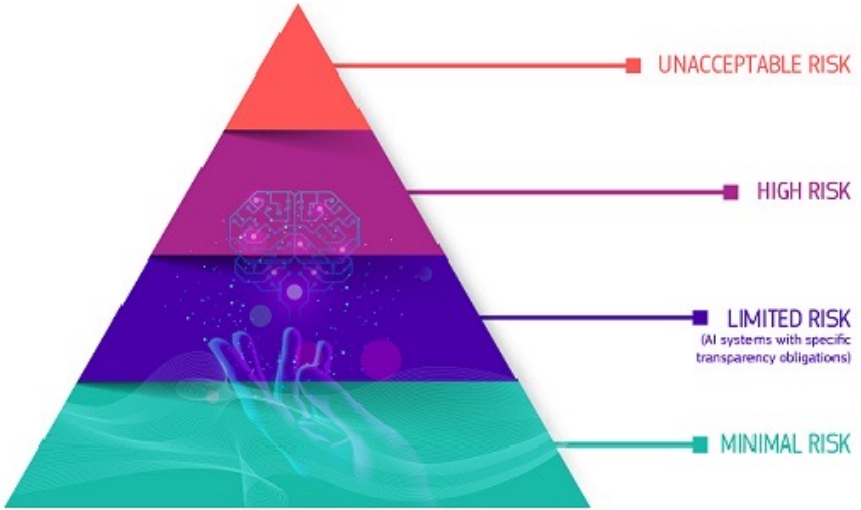
SHARE

KEY POINTS

- The European Union's parliament on Wednesday approved the world's first major set of regulatory ground rules to govern the mediatized artificial intelligence at the forefront of tech investment.
- Born in 2021, the EU AI Act divides the technology into categories of

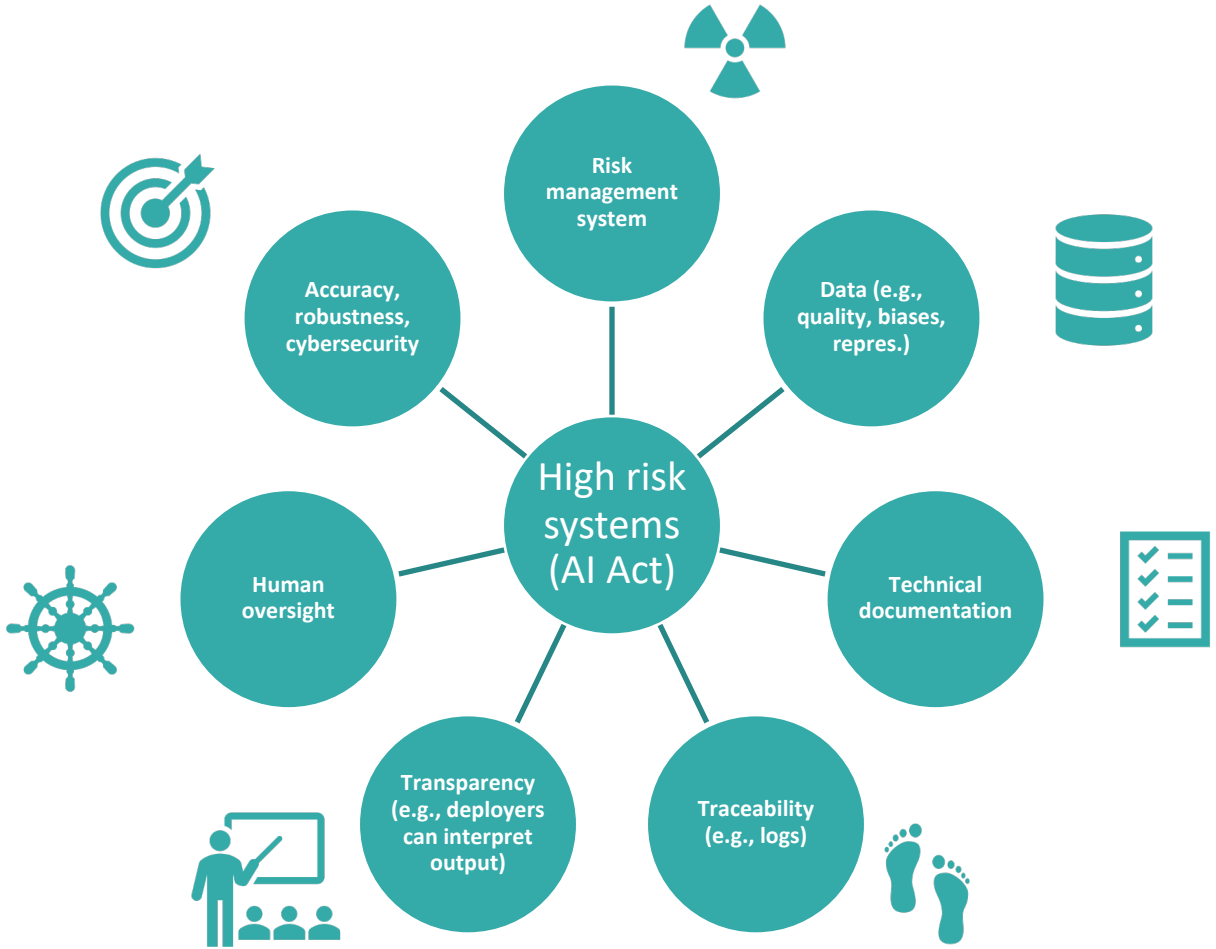
EUROPEAN AI ACT

Not specific to the medical sector, but...



… most medical AI softwares will be classified as high-risk systems

Credit: European Commission, https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai



Interplay with MDR? Overlap?

Conformity assessment/documentation can be integrated into the existing processes for medical device assessment

LIABILITY

LIABILITY

Use of AI can weaken the position of patients

Specific characteristics of AI, including autonomy and opacity (the so-called “black box” effect), make it difficult or very expensive

- to identify the liable person
- prove the requirements for a successful liability claim

LIABILITY

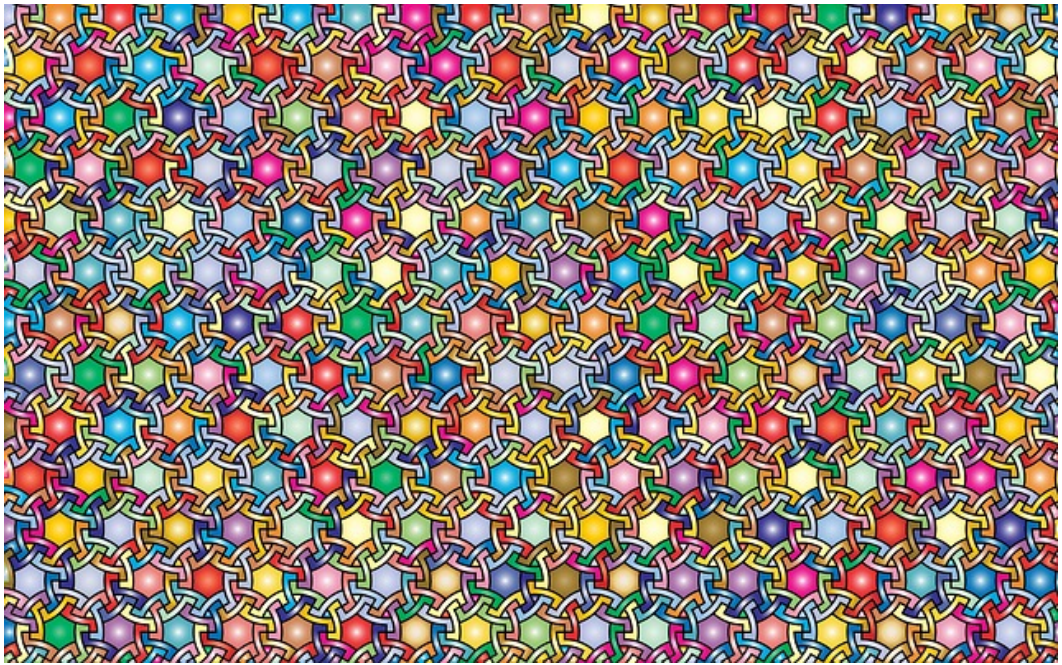
Proposal to adopt or adapt liability regulations in EU, e.g.,

- presumption of causality
- obligation for manufacturers to disclose certain information

CONCLUSION

INTERPLAY

- Mutiple regulations
  - Not addressed here: IP, competition laws, cybersecurity, contractual aspects…
- Overlap
- Moving fast



SUMMARY

Before starting:

- Identify legal requirements (MDR, privacy, AI, other)
- Define business objectives
- Establish a legal/compliance strategy
- Apply requirements across the full life cycle

THANK YOU

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