What to keep in mind when entering into the world of AI?

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Lise-Lotte Lääne

Tallinn

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The AI Act

- **Regulation (EU) 2024/1689** (available at https://eur-lex.europa.eu/eli/reg/2024/1689/oj?eliuri=eli%3Areg%3A2024%3A1689%3Aoj&locale=en)
- 12 July 2024 – the AI Act was published in the Official Journal of the European Union
- 1 August 2024 – the AI Act entered into force
- 2 August 2026 – the main application date (Art 113)
- 2 August 2027 – Art 6(1) and obligations for high-risk AI systems used as safety components/products under EU-harmonised legislation shall apply (art 113(c))

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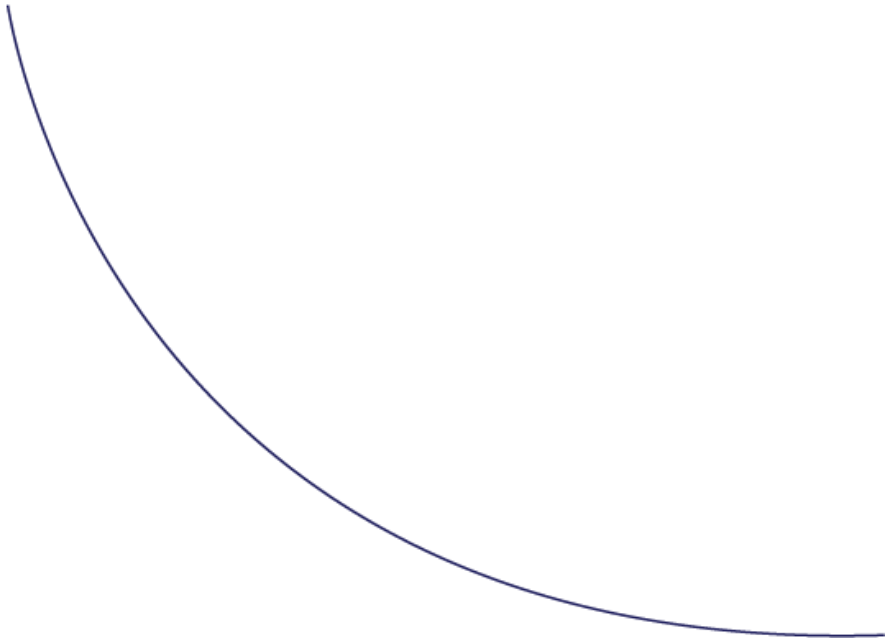
Scope: definition of AI



‘AI system‘ is a

1) machine-based system;
2) designed to operate with varying levels of **autonomy**; and
3) that may **exhibit adaptiveness** after deployment; and that,
4) for explicit or implicit objectives, **infers, from the input it receives, how to generate outputs** such as predictions, content, recommendations, or decisions that **can influence physical or virtual environments**

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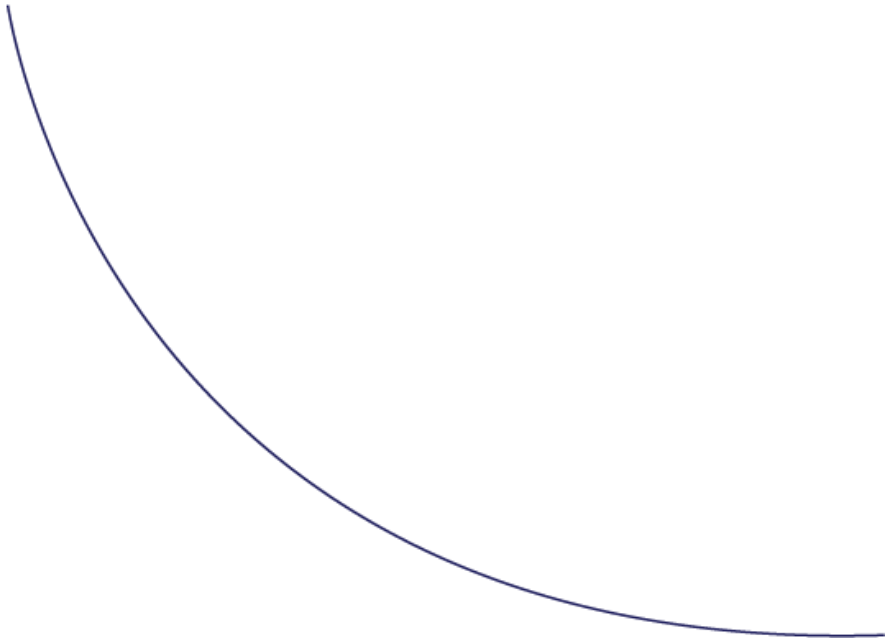
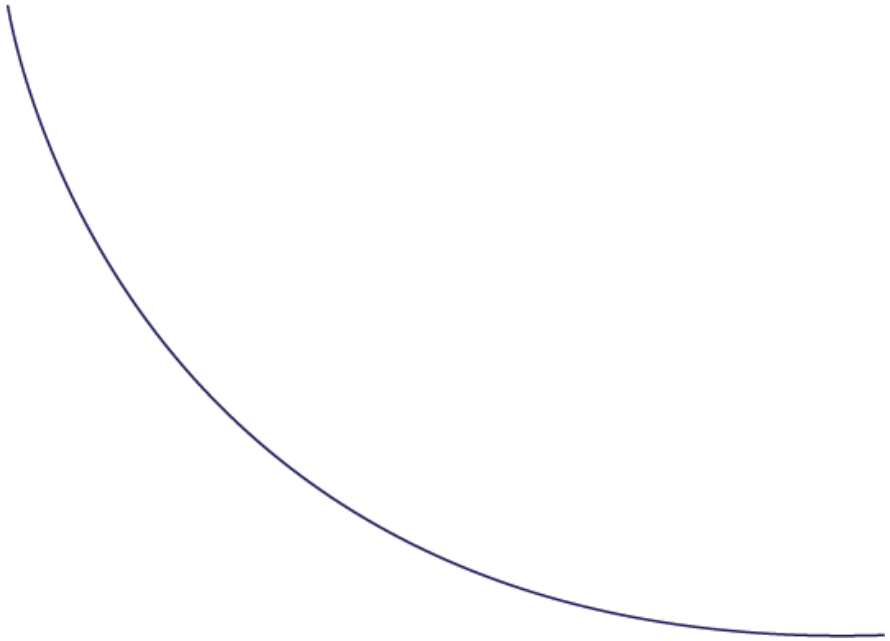
Scope: territory



Extraterritorial effect:

- Businesses located **in the EU**
- Businesses supplying AI systems **to the EU**
- Businesses located outside the EU, if output of their AI system **is used in the EU**

Scope: applicable persons



AI operators:

- **Providers** – develop AI & place on the market or put into service
- **Importers & distributors** – place AI on the market or make AI available on the market
- **Deployers** – users of AI systems

Impact on Life Sciences & Healthcare sector (?)

Medical devices as high-risk AI systems

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High-risk AI (Chapter III; Annexes I and III)

Where the AI systems fulfills **both** conditions:

1) AI system is intended to be used as a safety component (or is itself a product) under EU legislation listed in Annex I; AND
2) product is required to undergo third-party conformity assessment

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Annex I EU legislation covers:

- Machinery
- Toys
- Recreational craft and personal watercraft
- Lifts
- Equipment and protective systems for explosive atmospheres
- Radio equipment
- Cableway installations
- **Personal protective equipment**
- Appliances burning gaseous fuels
- **Medical devices**
- **In vitro diagnostic medical devices**
- Civil aviation security
- Two- or three-wheel vehicles and quadricycles
- Agricultural and forestry vehicles
- Marine equipment
- Rail systems
- Motor vehicles and trailers
- Civil aviation and aircraft

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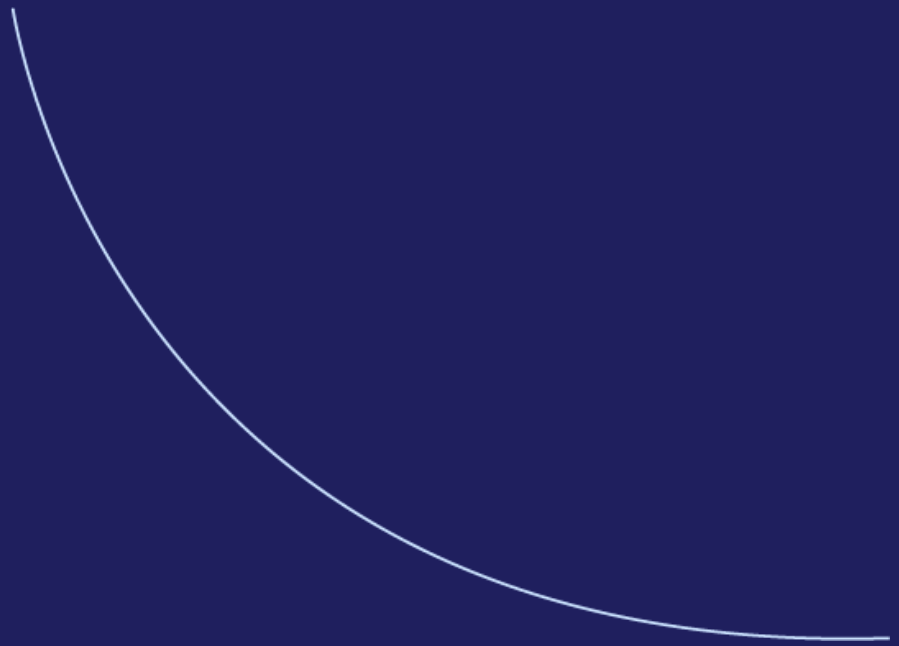
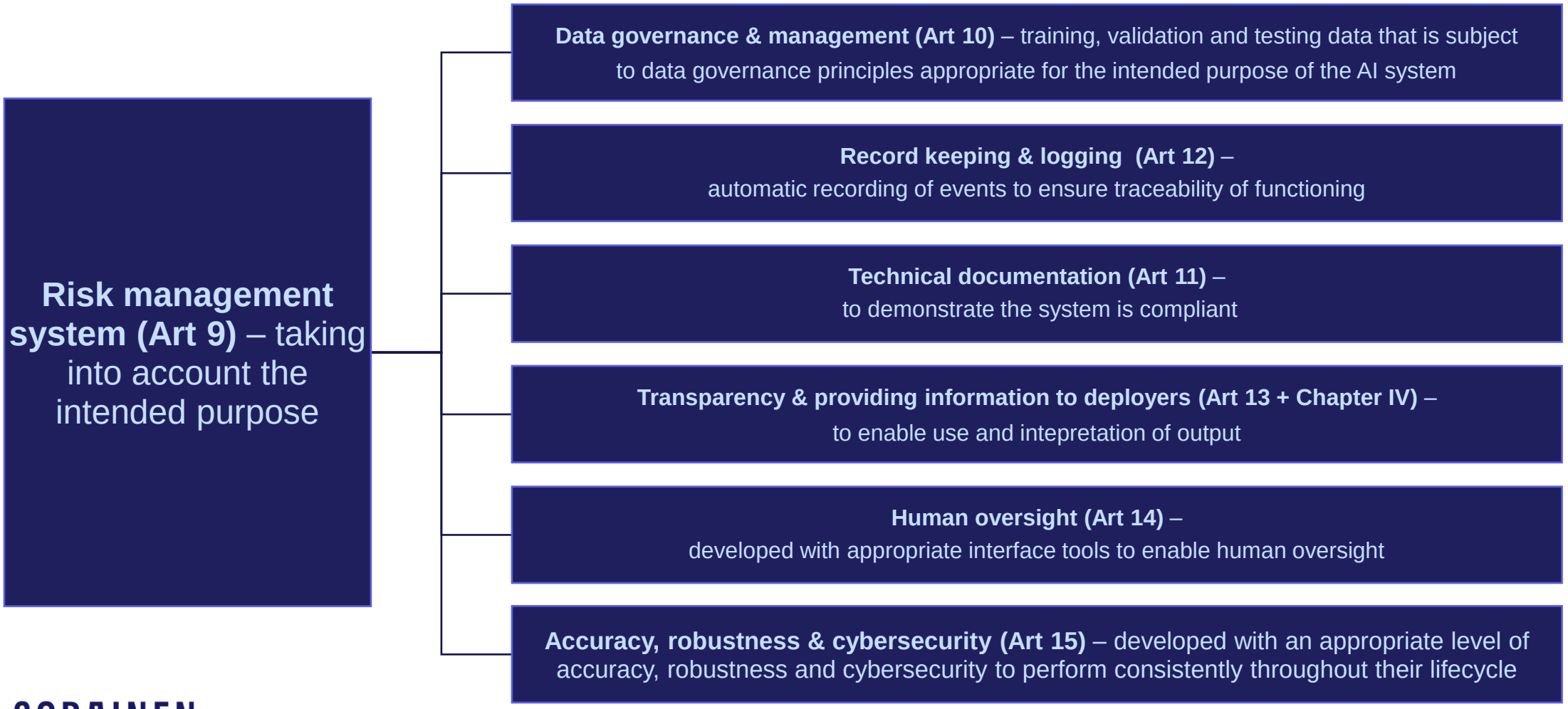
Medical devices & *in vitro* diagnostic medical devices as high-risk AI systems



- MDR: class IIa, IIb, III devices
- IVDR: class B, C, D devices
- Safety component or AIaMD:
  - Preamble para 47: *AI systems could have an adverse impact on the health and safety of persons, in particular when such systems operate as safety components of products. [...], it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate.*

High risk AI: key requirements



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High risk AI: operator obligations

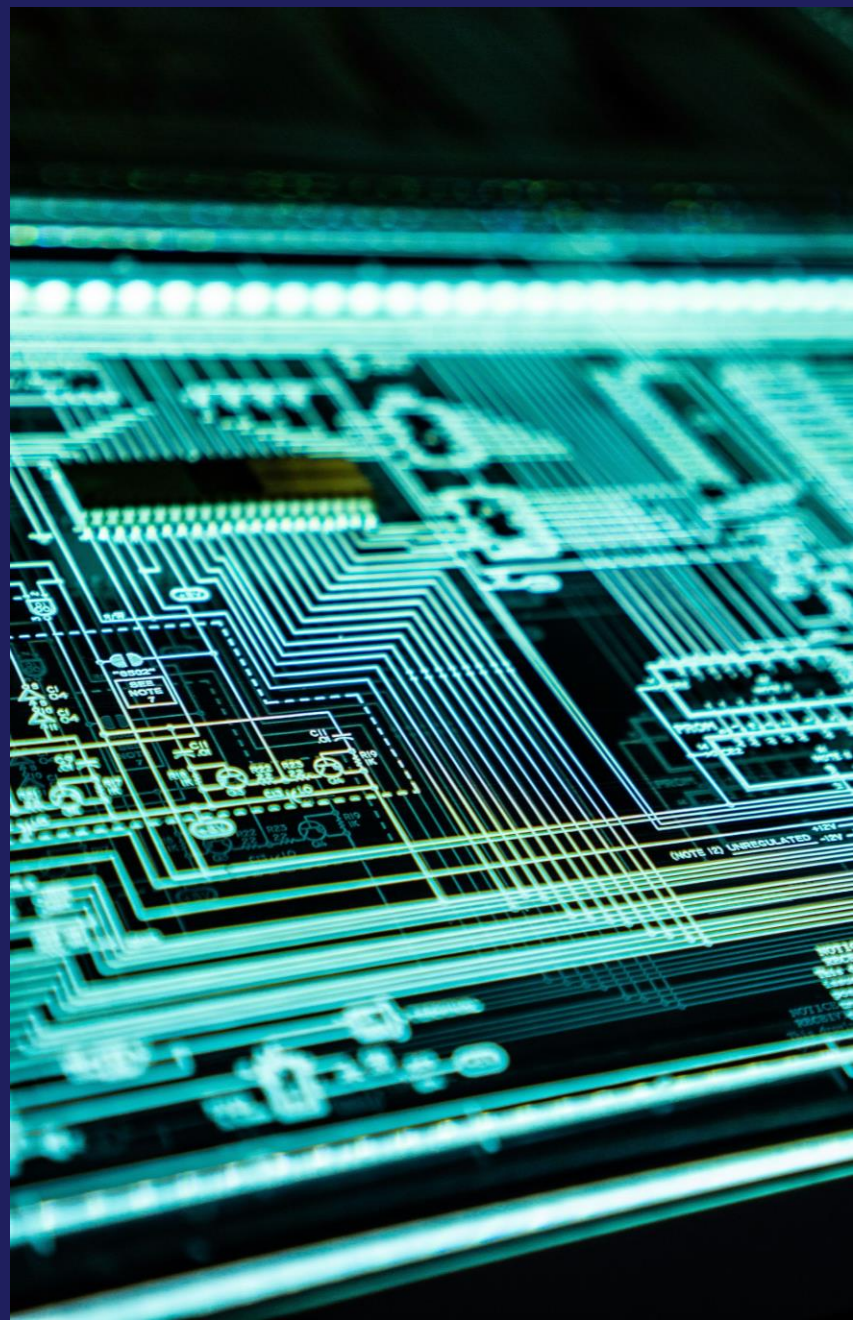
Providers:

- Risk assessment & quality management system
- Ex ante conformity assessment
- Register in the EU AI database
- Demonstrate conformity

Standards: presumed to be in conformity with requirements for high-risk AI systems

Deployers:

- Measures to ensure AI system used in accordance with instructions
- Ensure human oversight
- Monitoring & record-keeping obligations



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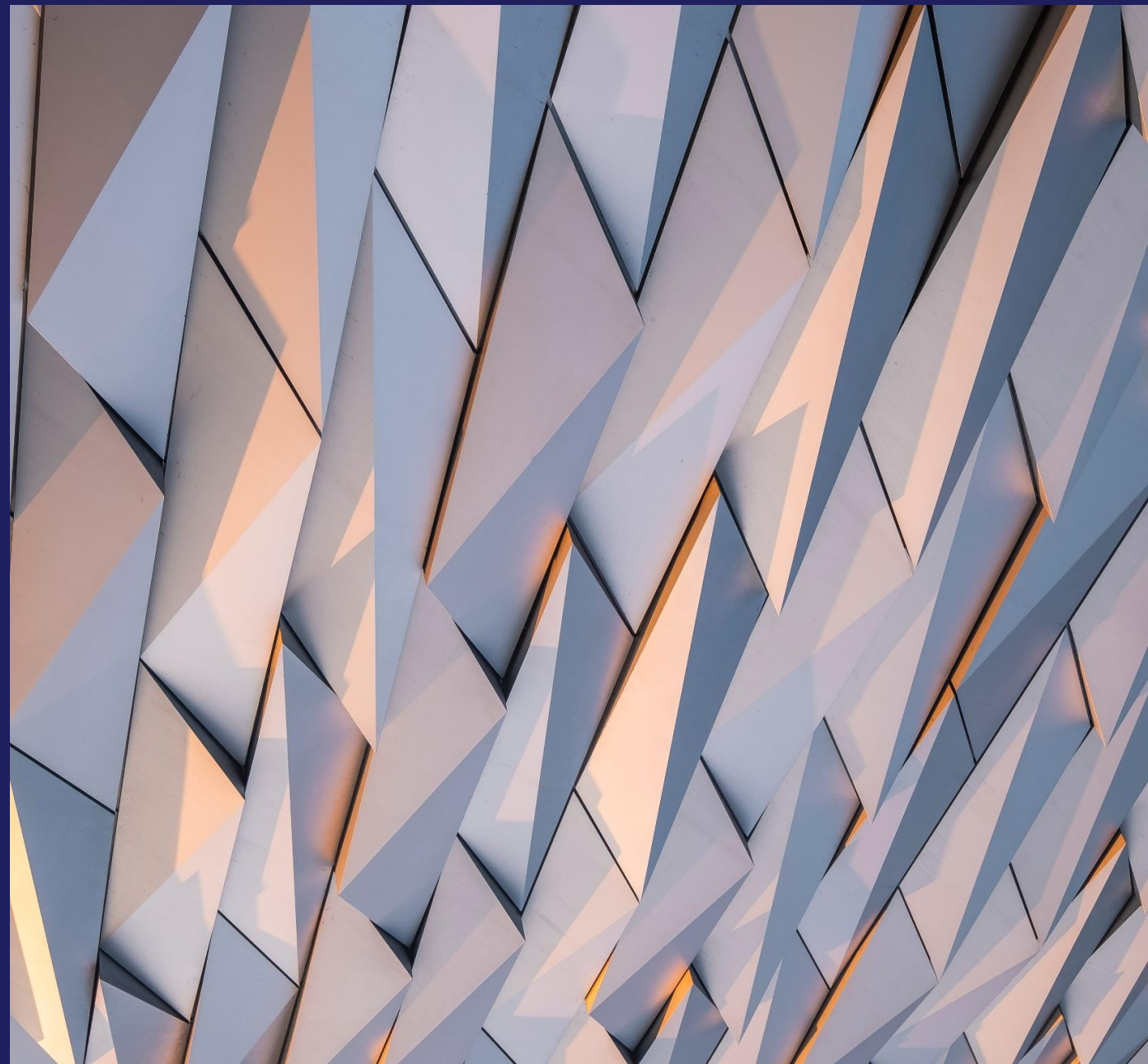
Application of AI systems (to/in) the provision of healthcare



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Deployers

Art 3(4): *'deployer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity;*

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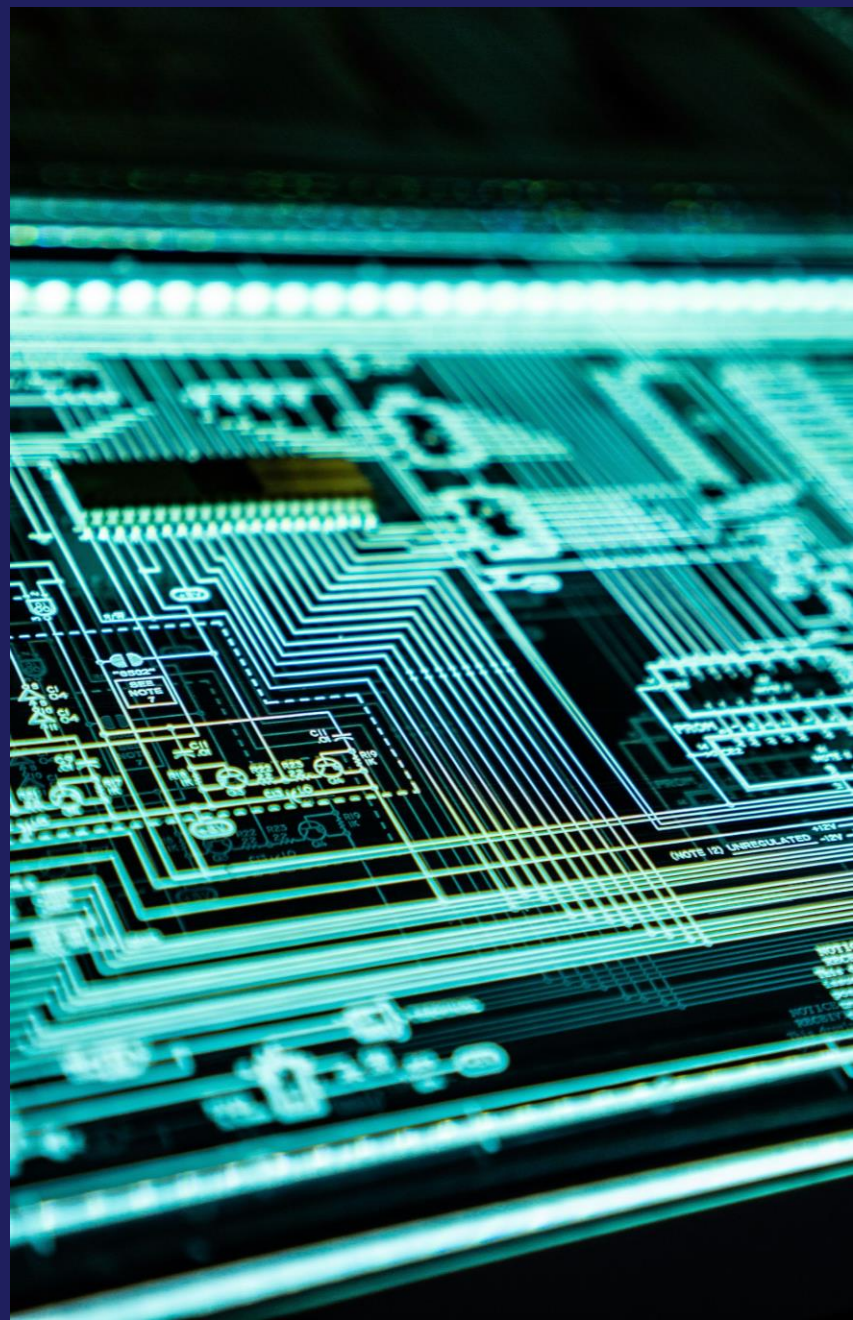

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Human oversight

(Art 14)

1. High-risk AI systems [...] can be **effectively overseen by natural persons** during the period in which they are in use.

2. Human oversight shall **aim to prevent or minimise the risks to health, safety** [...].

3. The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system, and shall be ensured through either one or both of the following types of measures:

- (a) **measures identified and built, when technically feasible, into** the high-risk AI system by the provider before it is placed on the market or put into service;
- (b) measures identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be **implemented by the deployer.**

4. [...] the high-risk AI system shall be provided to the deployer in such a way that natural persons to whom human oversight is assigned are enabled, as appropriate and proportionate:

- (a) to properly understand the relevant capacities and limitations of the high-risk AI system and be able to duly monitor its operation, including in view of **detecting and addressing anomalies, dysfunctions and unexpected performance**;
- (b) to remain aware of the possible tendency of **automatically relying or over-relying** on the output produced by a high-risk AI system (automation bias), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;
- (c) **to correctly interpret the high-risk AI system's output**, taking into account, for example, the interpretation tools and methods available;
- (d) to decide, in any particular situation, not to use the high-risk AI system or to otherwise disregard, **override or reverse the output of the high-risk AI system**;
- (e) **to intervene in the operation** of the high-risk AI system or interrupt the system through a 'stop' button or a similar procedure that allows the system to come to a halt in a safe state.

Key challenges

- Ethical & structural challenges
  - Where do we draw the line?
- Liability issues
  - The provision of healthcare is an act by a natural person (HCP)
- AI literacy
  - Preamble para 20: *In order to obtain the greatest benefits from AI systems while protecting fundamental rights, health and safety and to enable democratic control, AI literacy should equip providers, deployers and affected persons with the necessary notions to make informed decisions regarding AI systems.*
  - Preamble para 91: *Furthermore, deployers should ensure that the persons assigned to implement the instructions for use and human oversight as set out in this Regulation have the necessary competence, in particular an adequate level of AI literacy, training and authority to properly fulfil those tasks. Those obligations should be without prejudice to other deployer obligations in relation to high-risk AI systems under Union or national law.*

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Thank you!

Lise-Lotte Lääne,

Regional co-head of Life Sciences & Healthcare sector group, Counsel,

Sorainen in Estonia

lise-lotte.laane@sorainen.com