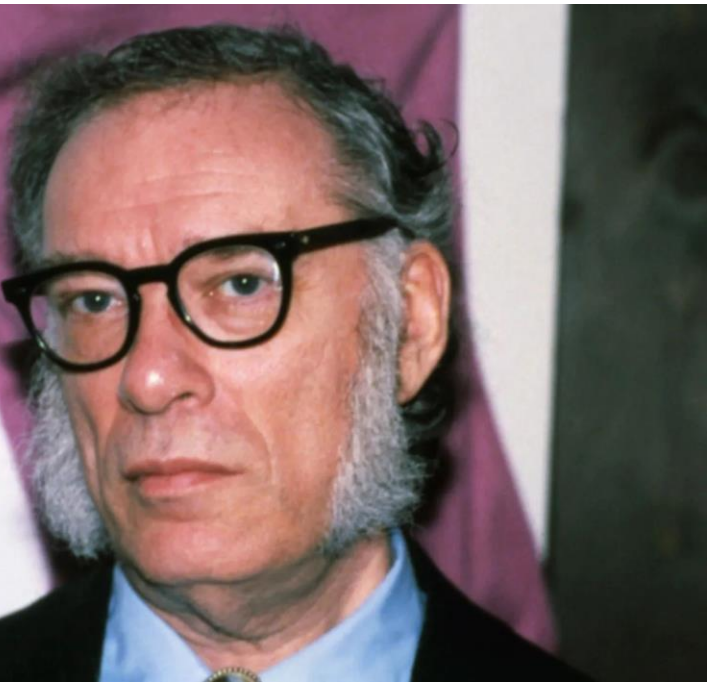
E.U. Agrees on Landmark Artificial Intelligence Rules

The agreement over the A.I. Act solidifies one of the world's first comprehensive attempts to limit the use of artificial intelligence.



- First Law: a robot may not injure a human being or, through inaction, allow a human being to come to harm;
- Second Law: a robot must obey the orders given it by human beings except where such orders would conflict with the First Law;
- Third Law: a robot must protect its own existence as long as such protection does not conflict with the First or Second Law.”
- “a robot may not harm humanity, or, by inaction, allow humanity to come to harm.”

"Handbook of Robotics, 56th Edition, 2058 A.D."

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Artificial Inteligence Act

Adopted on March 13, 2024

Has become binding law in all EU Member States 20 days after its publication in the Official Journal of the EU (published on July 12th 2024), irrespective of existing national laws and guidelines on AI (Art 1 (2a), Art 113). Most parts of the regulation will take effect within 24 months, with prohibitions ,i.e., bans on AI applications deemed to pose an unacceptable risk, taking effect already within 6 months (Art 113 (a–c)).

Piotr Szymanski, Chair, Regulatory Affairs Committe, ESC

CRT Round Table on Artificial Intelligence, Zurich

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AI Act aims to promote human-centred and trustworthy AI while protecting the health, safety, and fundamental rights of individuals from the potentially harmful effects of AI-enabled systems (Article (Art) 1 (1)).

the AI Act applies to providers and deployers of AI systems in third countries if the generated output is used in the Union (Art 2 (1c)). Any AI product could be subject to the AI Act if its output can be received in the Union, regardless of the provider's or deployer's intention or location

the AI Act also applies to"[…]deployers of AI systems that have their place of establishment or are located within the Union […]" (Art 2 (1b)). Therefore, deployers of AI systems within the EU, even if their models are not intended for the EU market, must comply with the AI Act regulations

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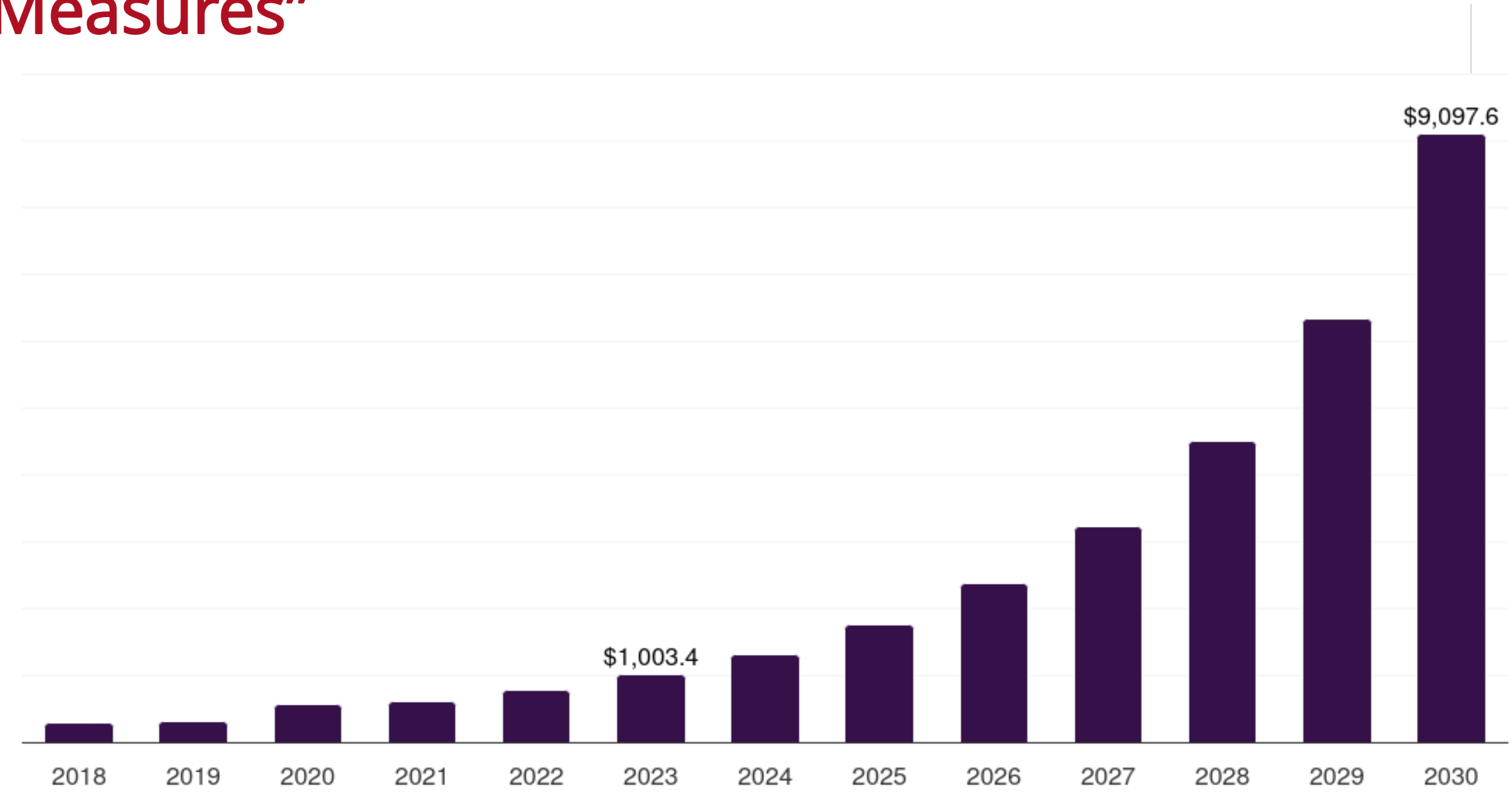
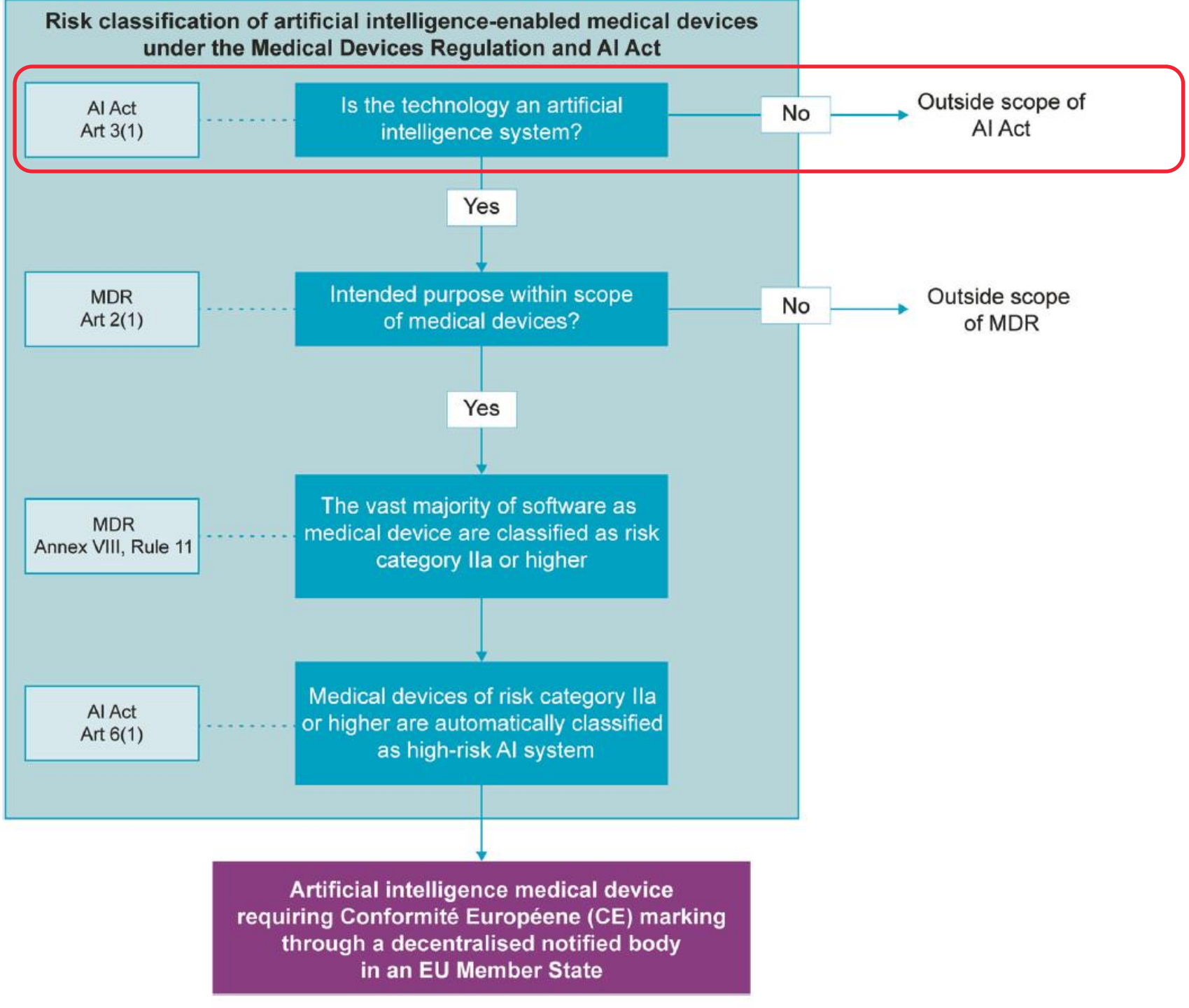
Cyberspace Administration of China. “Generative AI Measures”





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Article 3.1.

- ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, 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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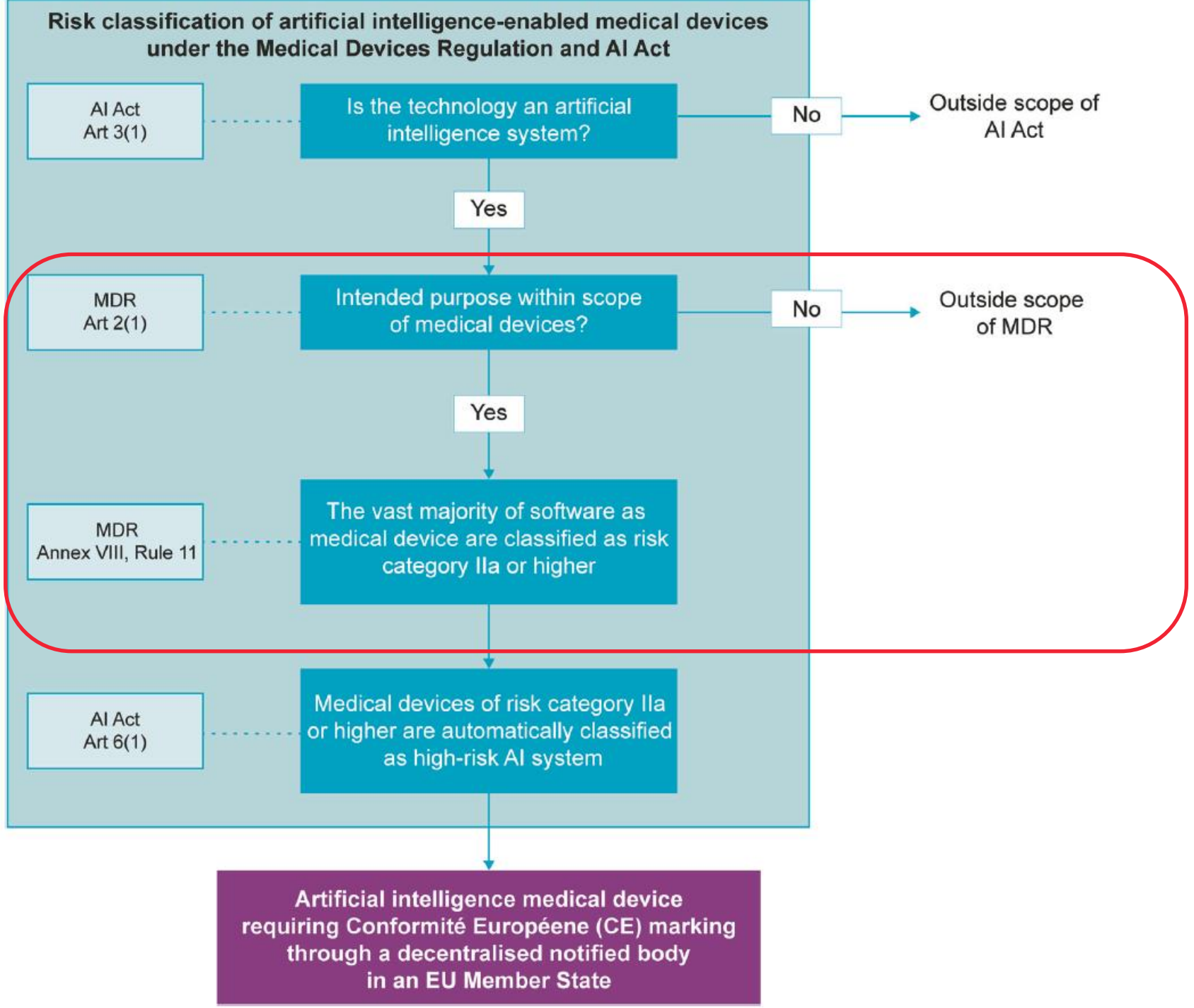

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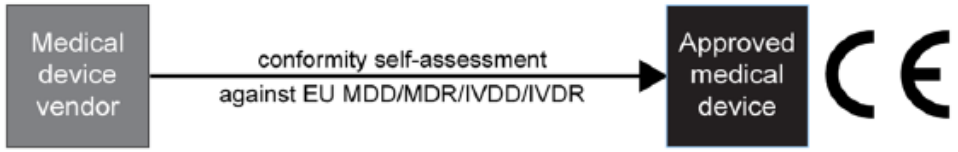
Lower risk devices

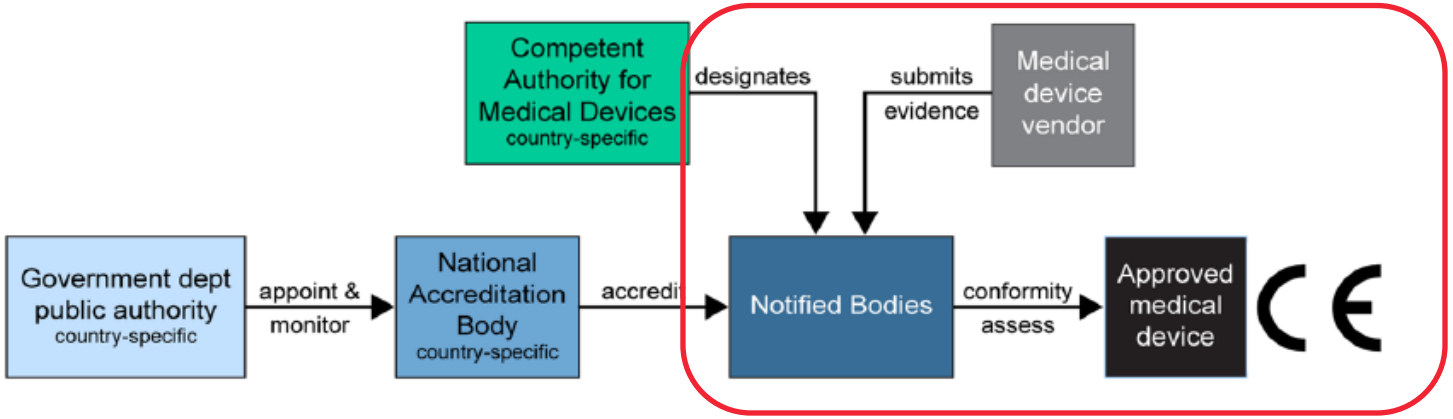
Medical devices: Class I (EU MDD, UK MDR, & EU MDR)*
IVD medical devices: General IVDs (EU IVDD & UK MDR) or Class A IVDs (EU IVDR)**

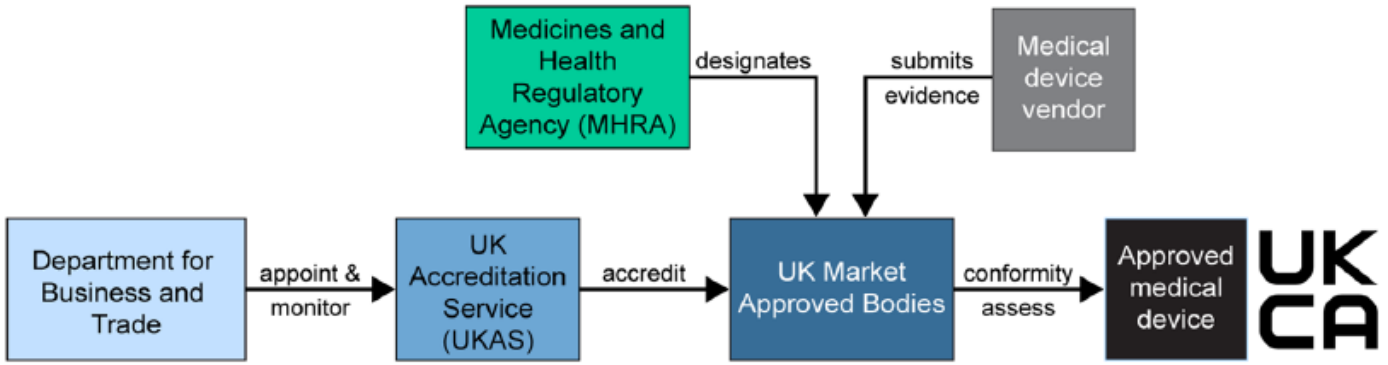


*Excluding Class Im, 1s, and 1r devices
** Excluding Class A sterile devices

Higher risk devices

Medical devices: Class Im, 1s, IIa, IIb, & III (EU MDD & UK MDR) or Class Im, 1s, 1r, IIa, IIb, & III (EU MDR)
IVD medical devices: List A, B, & self-test IVDs (EU IVDD & UK MDR) or Class A sterile & B-D IVDs (EU IVDR





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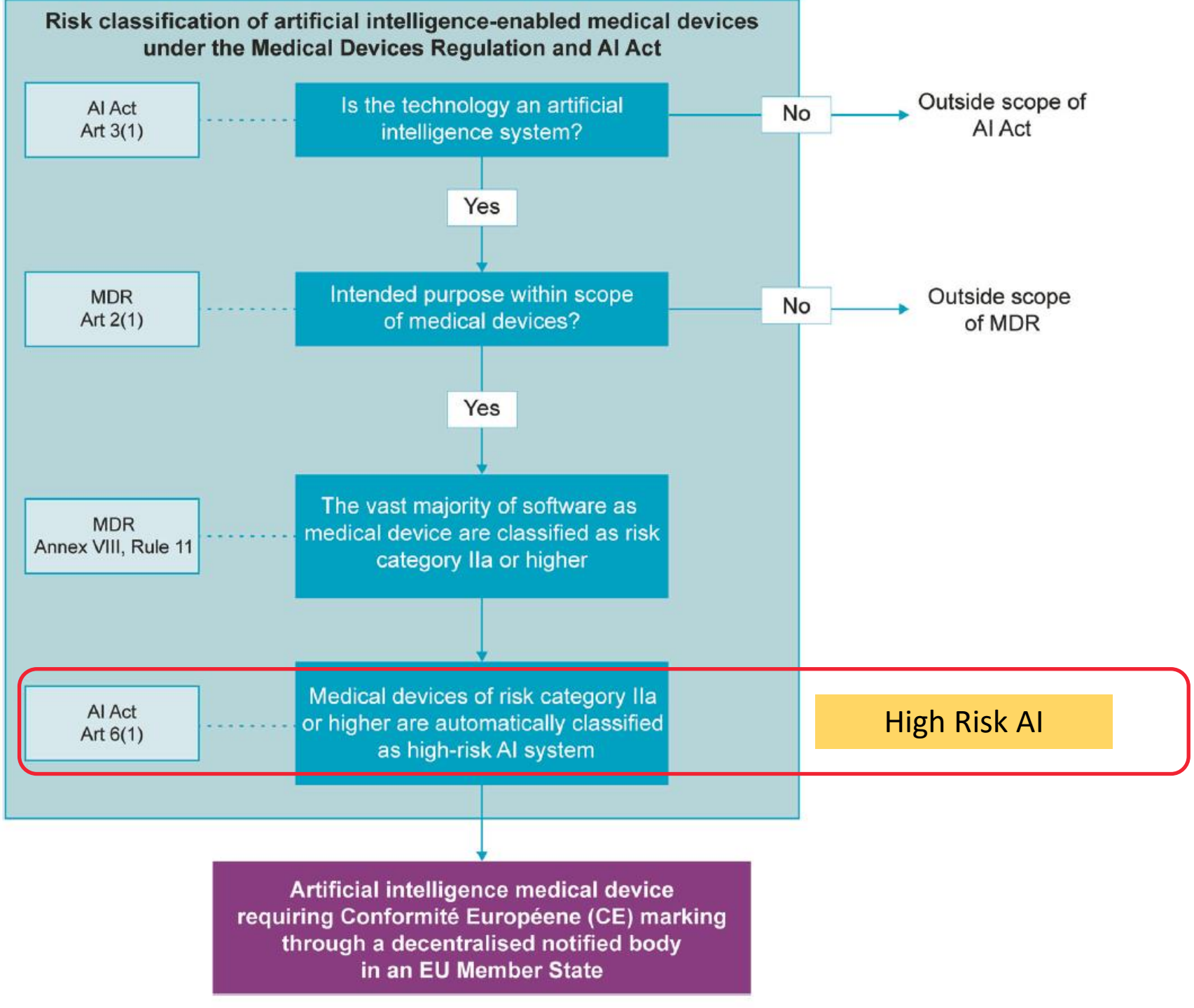

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Article 6. Classification rules for high-risk AI systems

- AI system shall be considered to be high-risk where both of the following conditions are fulfilled:
- (a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;
- (b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service

common administrative tasks of AI systems in the medical field, such as medical text classification (e.g., ICD-10 coding) or structuring (e.g., structured radiology reporting), are unlikely to be classified as high risk

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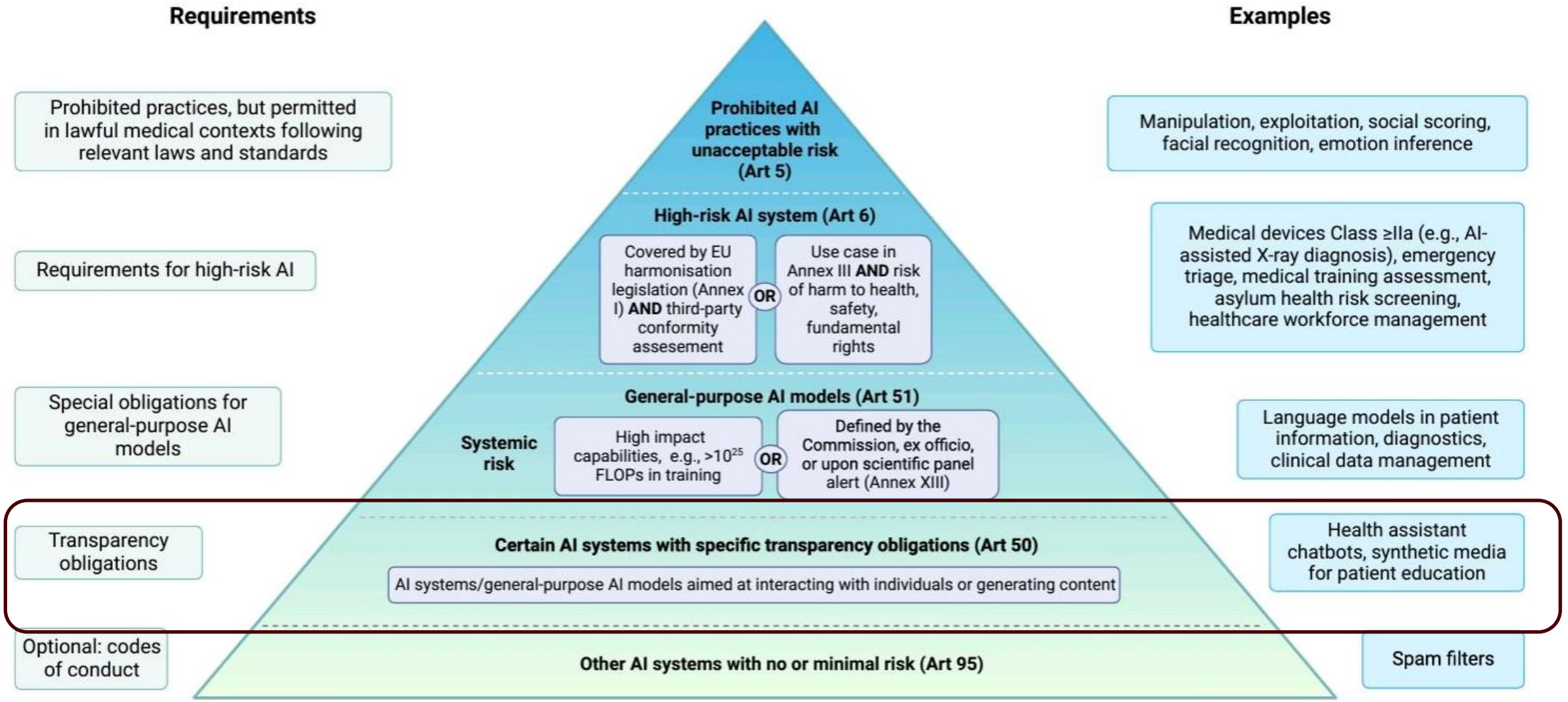

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Article 50. Transparency obligations for providers and deployers of certain AI systems

- Providers shall ensure that AI systems intended to interact directly with natural persons are designed and developed in such a way that the natural persons concerned are informed that they are interacting with an AI system, unless this is obvious from the point of view of a natural person who is reasonably well-informed.
- Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, shall ensure that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated.

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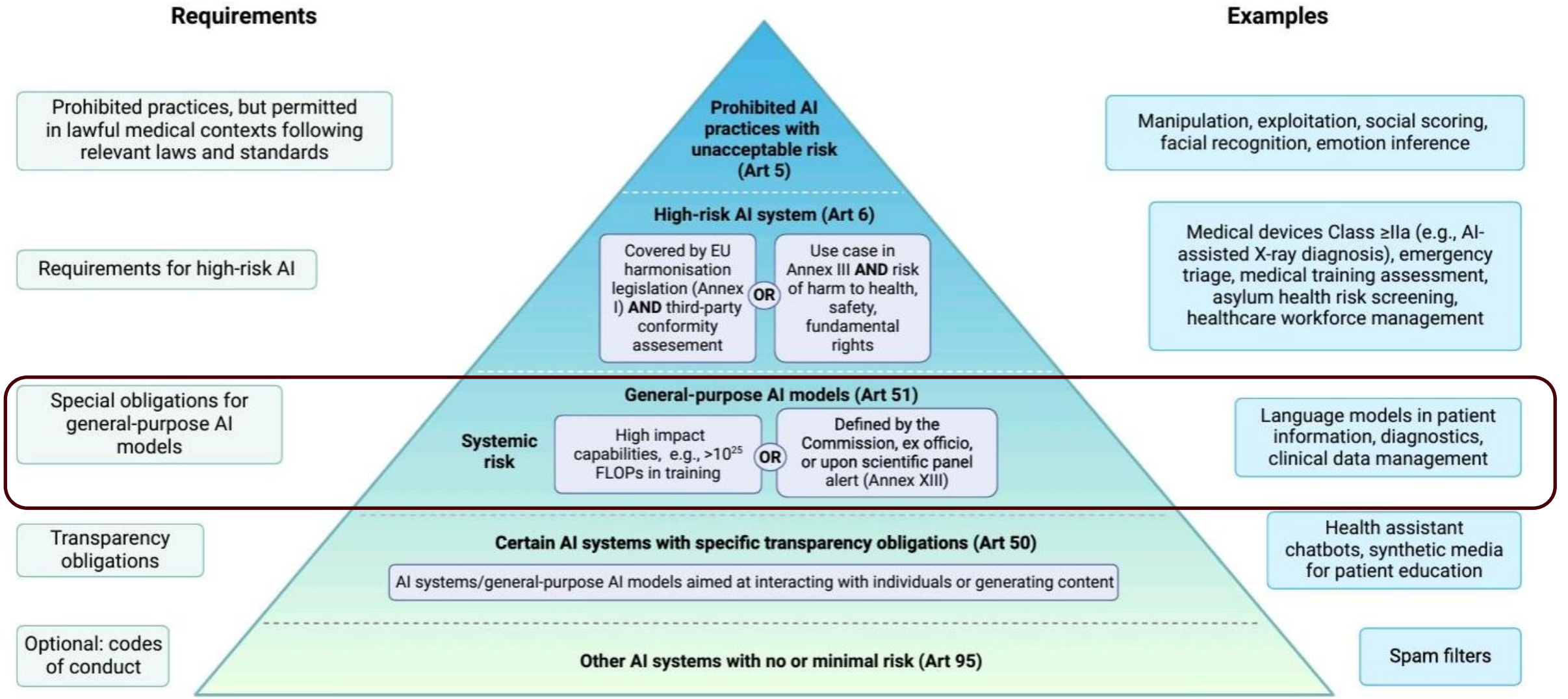

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Article 51. Classification of general-purpose AI models as general-purpose AI models with systemic risk

General-purpose AI model shall be classified as a general-purpose AI model with systemic risk if it meets any of the following conditions:

- it has high impact capabilities evaluated on the basis of appropriate technical tools and methodologies, including indicators and benchmarks;
- based on a decision of the Commission, ex officio or following a qualified alert from the scientific panel.

Article 55. Obligations of providers of general-purpose AI models with systemic risk

Poviders of general-purpose AI models with systemic risk shall:

- perform model evaluation, including conducting and documenting adversarial testing of the model with a view to identifying and mitigating systemic risks;
- assess and mitigate possible systemic risks, that may stem from the development, the placing on the market, or the use of general-purpose AI models
- keep track of, document, and report, to the AI Office, national competent authorities, relevant information about serious incidents and possible corrective measures to address them.

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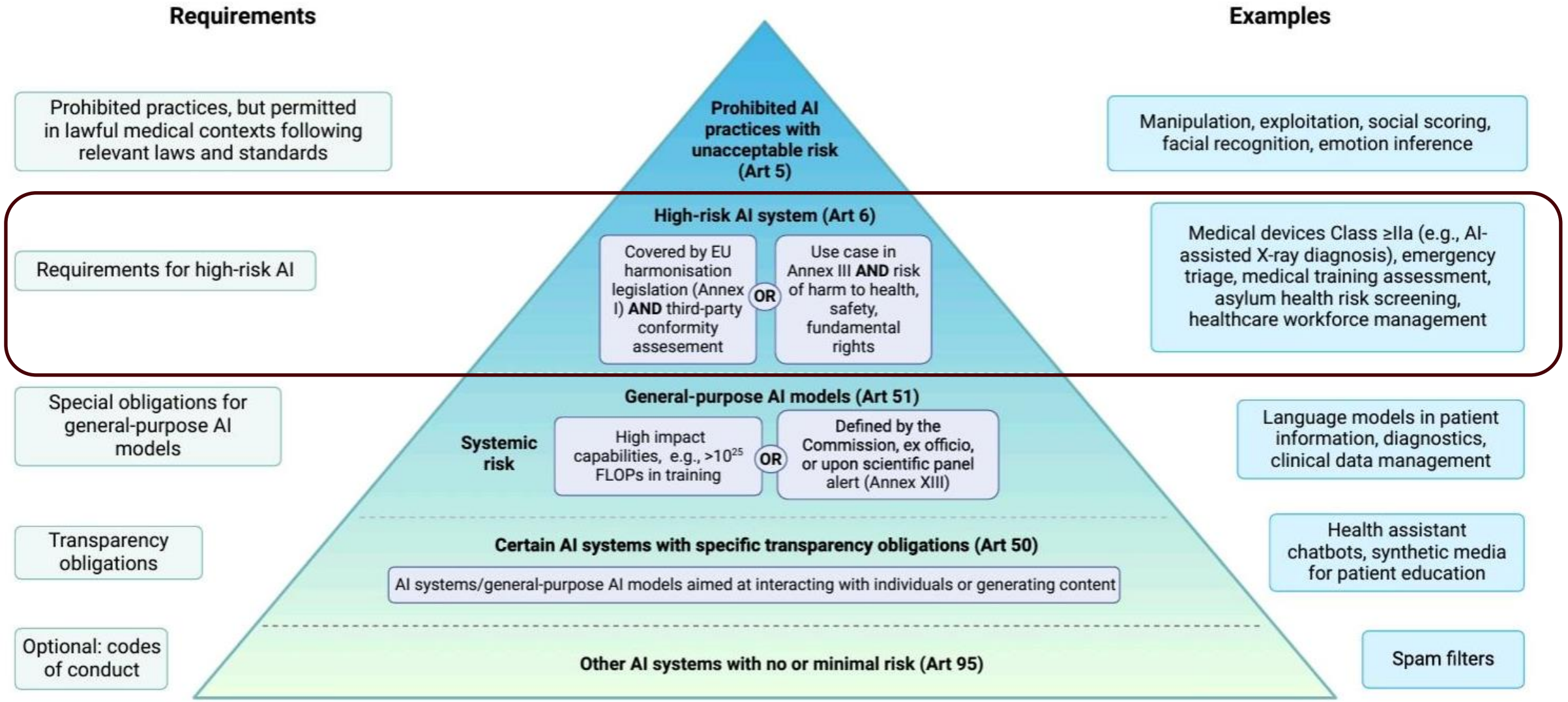

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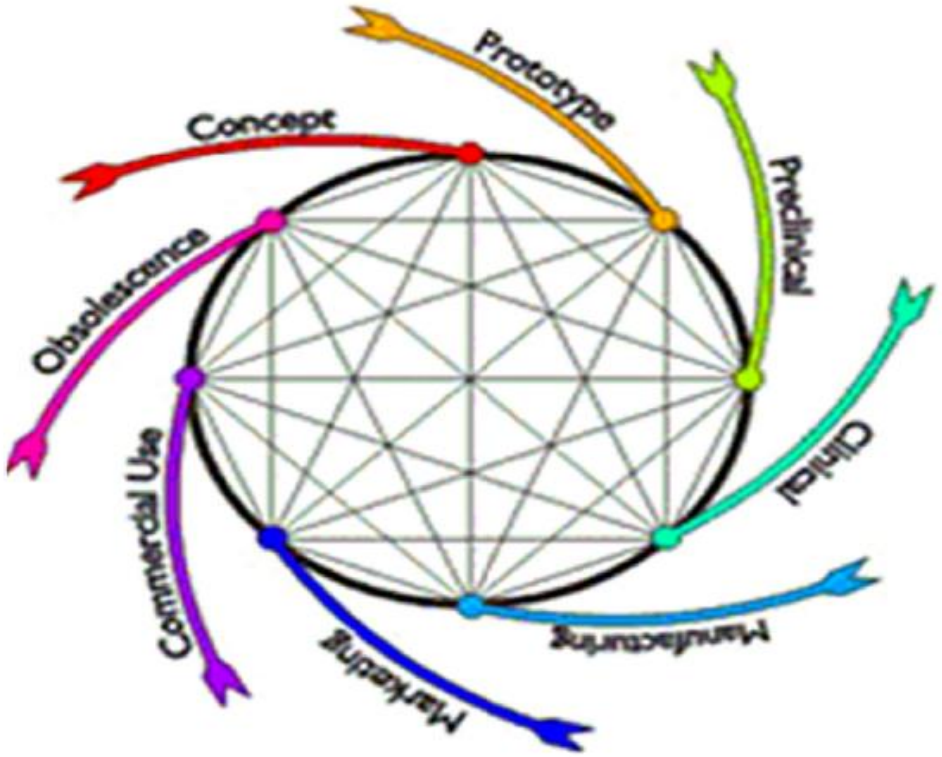
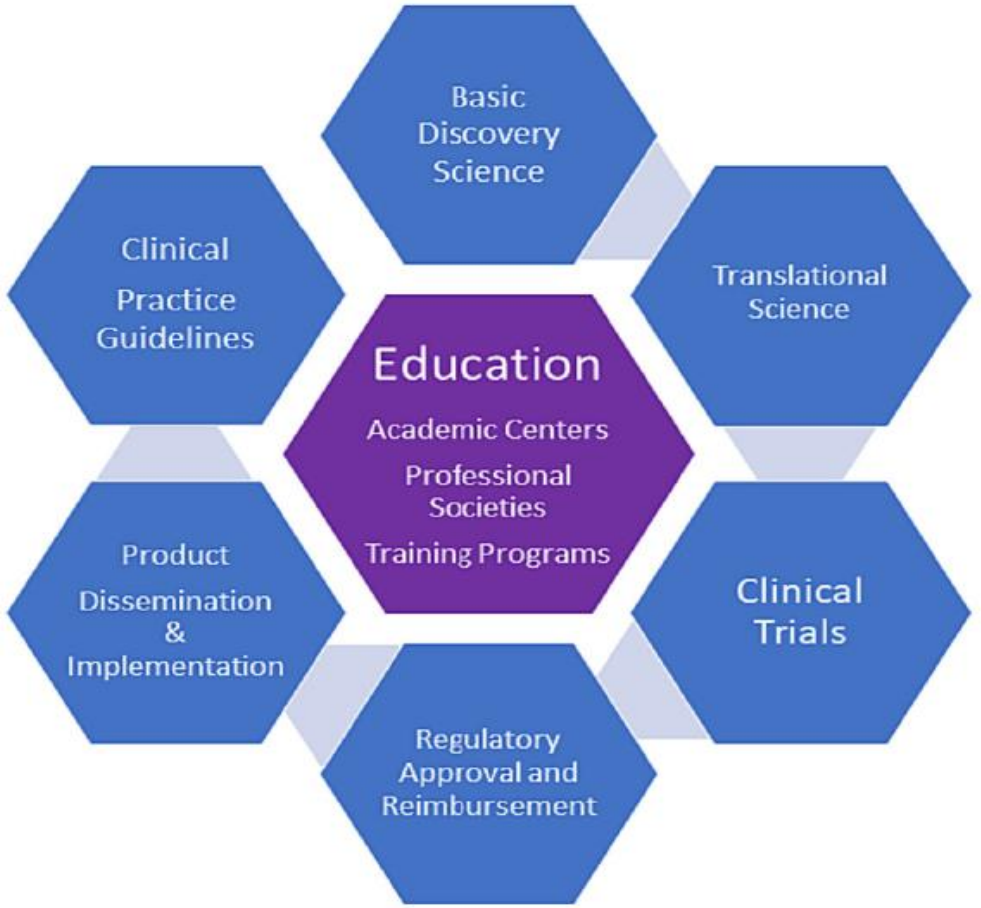
Article 9. Risk managment system





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Obligations for Deployers of High-Risk AI Systems

- Training and Support Obligations
  - **AI literacy training:** Ensure all users have sufficient AI knowledge and information to use the AI system as intended.
  - **Training and support of overseers**: Provide necessary training and support for those overseeing the respective high-risk AI system to ensure that they have the necessary competence and authority to carry out that role.
- Operational Obligations
  - **Technical and organizational measures:** Implement appropriate technical and organizational measures to ensure that use of the high-risk AI systems is in accordance with the instructions of use.
  - **Input data quality management:** Ensure input data is representative, qualitative, and relevant for the AI system's intended purpose.
  - **Suspension of operation:** Suspend use if the high-risk AI system poses a risk or does not perform as intended.

Obligations for Deployers of High-Risk AI Systems

- Control and Risk-Management Obligations
  - **Pre-check:** Ensure the AI system does not engage in any of the prohibited practices.
  - **Impact assessment:** carry out, document, a fundamental rights impact assessment.
  - **Human oversight:** implement the human oversight measures indicated by the providers.
  - **Continuous monitoring:** Regularly monitor the AI system for risks, detecting and addressing anomalies, dysfunctions, and unexpected performance.
- Documentation Obligations
  - **Recordkeeping:** Maintain logs of the high-risk AI system's operations for at least six months.
- Notification Obligations
  - **Risks or incidents:** Notify providers and authorities in case of risks to the health, safety, or fundamental rights of individuals or a serious incident.
  - **Employees and individuals:** Inform individuals that may be affected by results derived from high-risk AI system about the use of this AI system.

Article 3.4. Definitions...

‘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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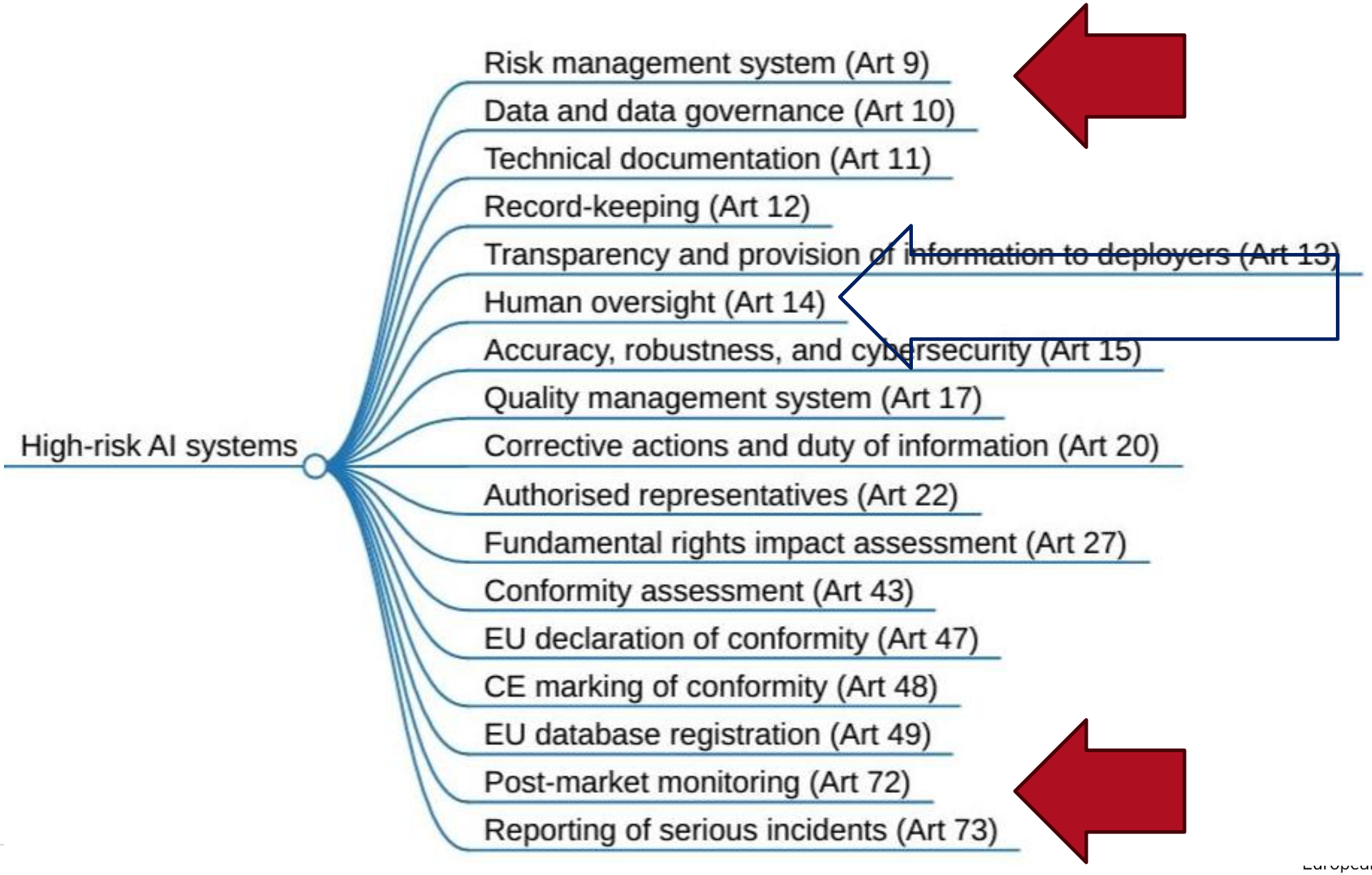
High-risk AI systems
Risk management system (Art 9)
Data and data governance (Art 10)
Technical documentation (Art 11)
Record-keeping (Art 12)
Transparency and provision of information to deployers (Art 13)
Human oversight (Art 14)
Accuracy, robustness, and cybersecurity (Art 15)
Quality management system (Art 17)
Corrective actions and duty of information (Art 20)
Authorised representatives (Art 22)
Fundamental rights impact assessment (Art 27)
Conformity assessment (Art 43)
EU declaration of conformity (Art 47)
CE marking of conformity (Art 48)
EU database registration (Art 49)
Post-market monitoring (Art 72)
Reporting of serious incidents (Art 73)

Article 14. Human oversight

- High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons.
- Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse
- The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system.

Relying on AI human supervision, the proposed AI Liability Directive, explains that "[t]here is no need to cover liability claims when the damage is caused by a human assessment followed by a human act or omission, while the AI system only provided information or advice which was taken into account by the relevant human actor."

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Article 4. AI Literacy

Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in.

Article 13.1. High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable **deployers to interpret a system's output and use it appropriately.**

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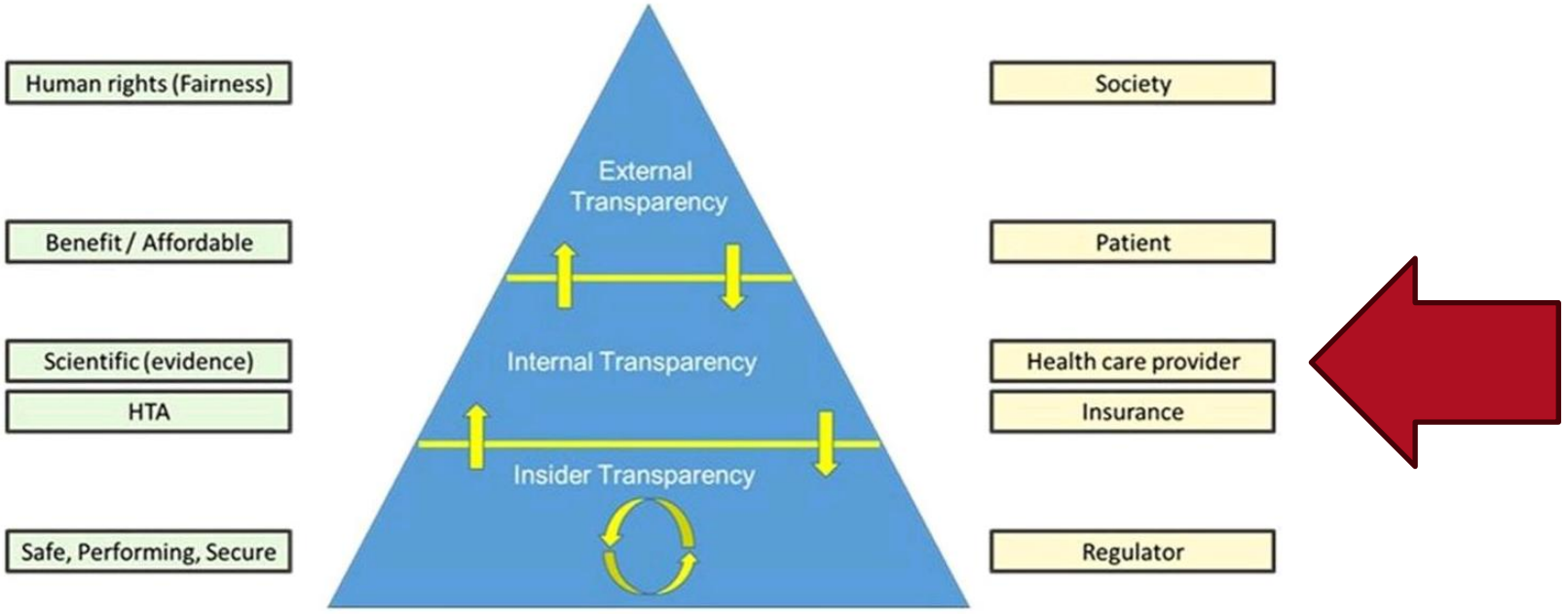
The Artificial Intelligence Act approved by the EU: the difficult dialogue between the black box and the cardiologist

Piotr Szymański[1,2]*, Frank Rademakers [3], and Alan G. Fraser[4]



Both internal and external transparency of design and development of high-risk AI systems is prerequisite for the oversight of their functioning, and to ensure that they are used as intended and that their impacts are addressed over the system's lifecycle

ESC European Society of Cardiology
European Heart Journal (2024) **45**, 2686–2688
https://doi.org/10.1093/eurheartj/ehae281
CardioPulse

Te EU AI Act does not operate in isolation...

There are 26,046 policy records:

2976 for EU, 3161 for Belgium, 368 for Estonia, 2947 for France, 1084 for Germany, 3466 for Italy, 205 for Malta, 418 for Poland, 9421 for Portugal, 1364 for Sweden, and 636 for the UK

Additionally, 757 academic records were identified.

Artificial Inteligence Act

Adopted on March 13, 2024

Piotr Szymanski, Chair, Regulatory Affairs Committe, ESC

CRT Round Table on Artificial Intelligence, Zurich

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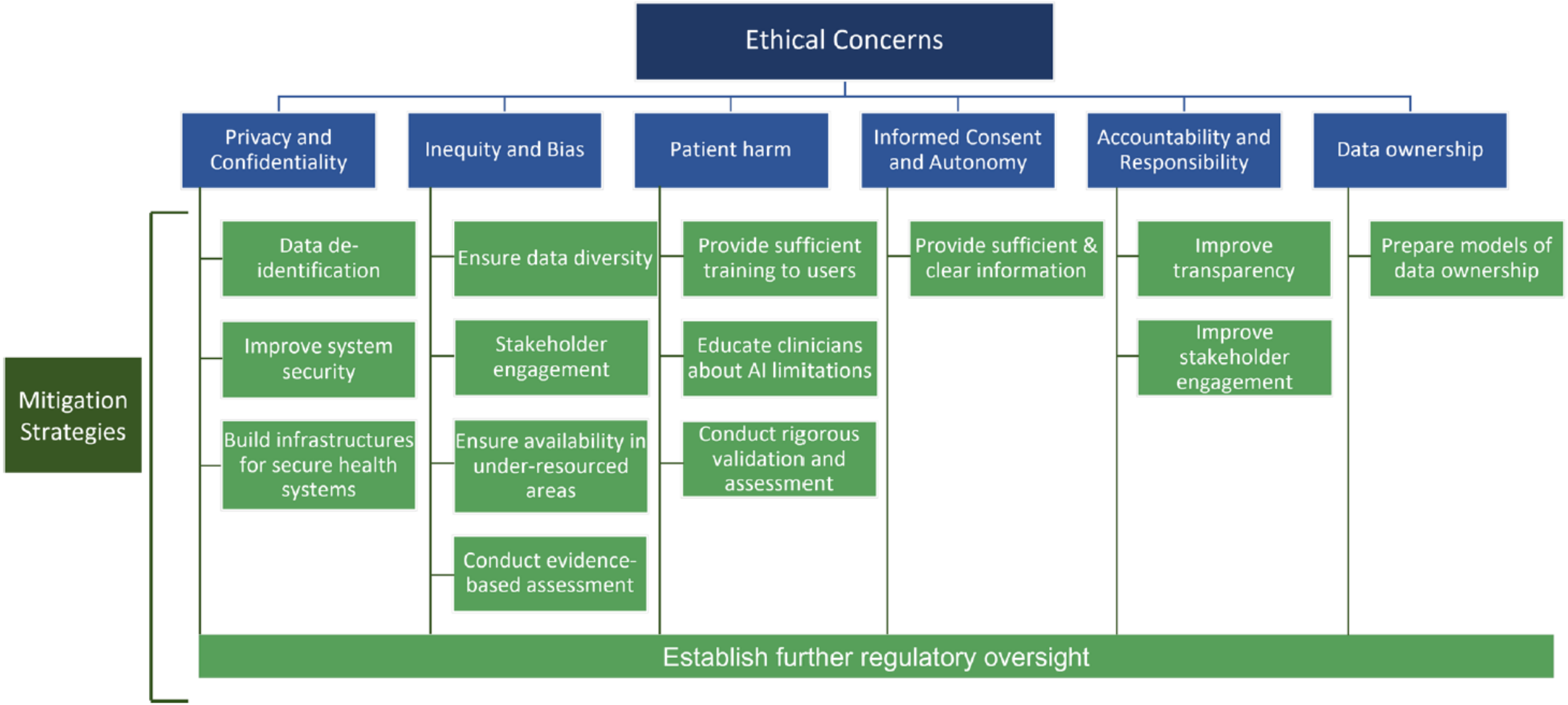


Fig. 2 Ethical Concerns and Mitigation Strategies for the Use of Artificial intelligence-based Medical Devices in Cardiovascular Care

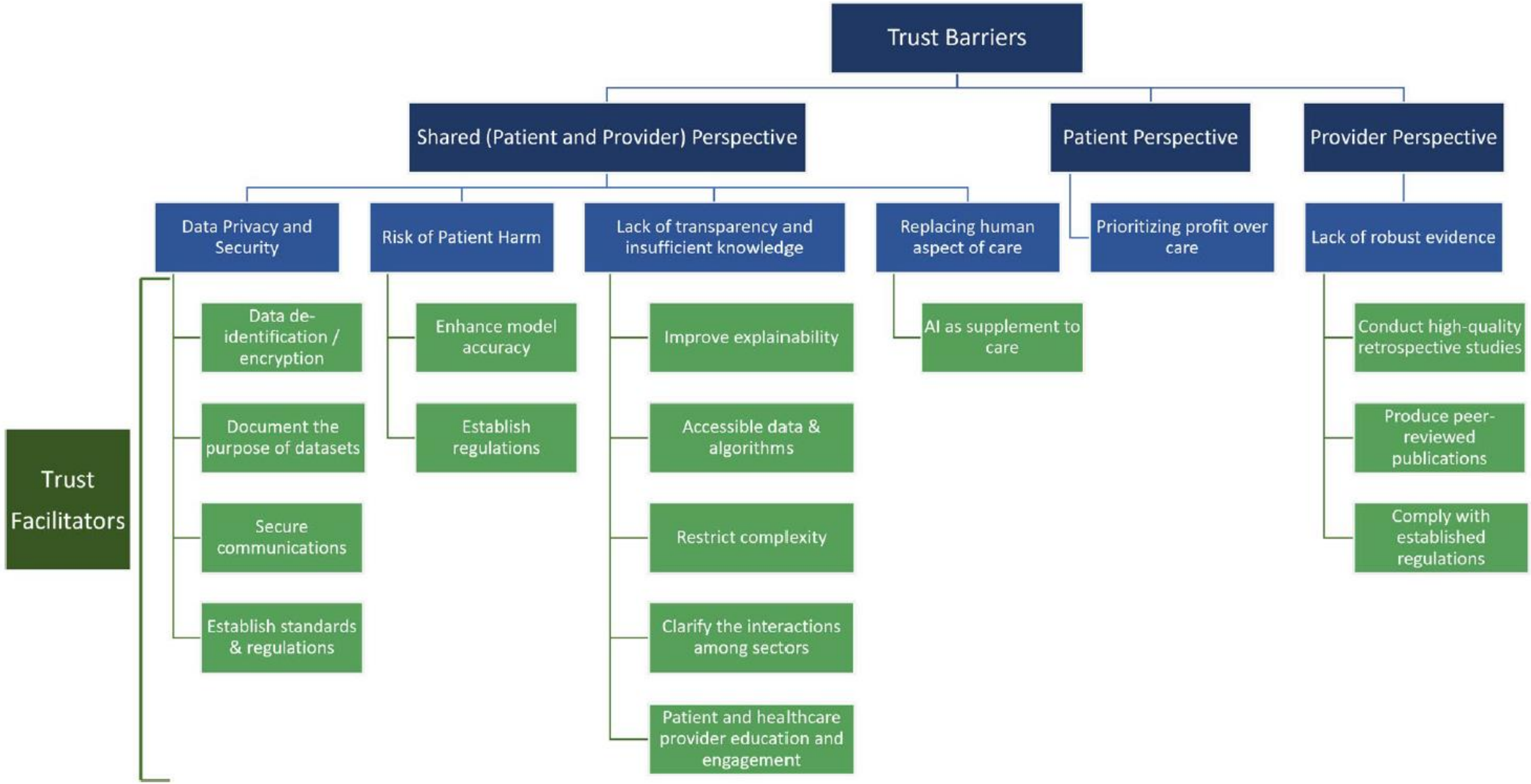
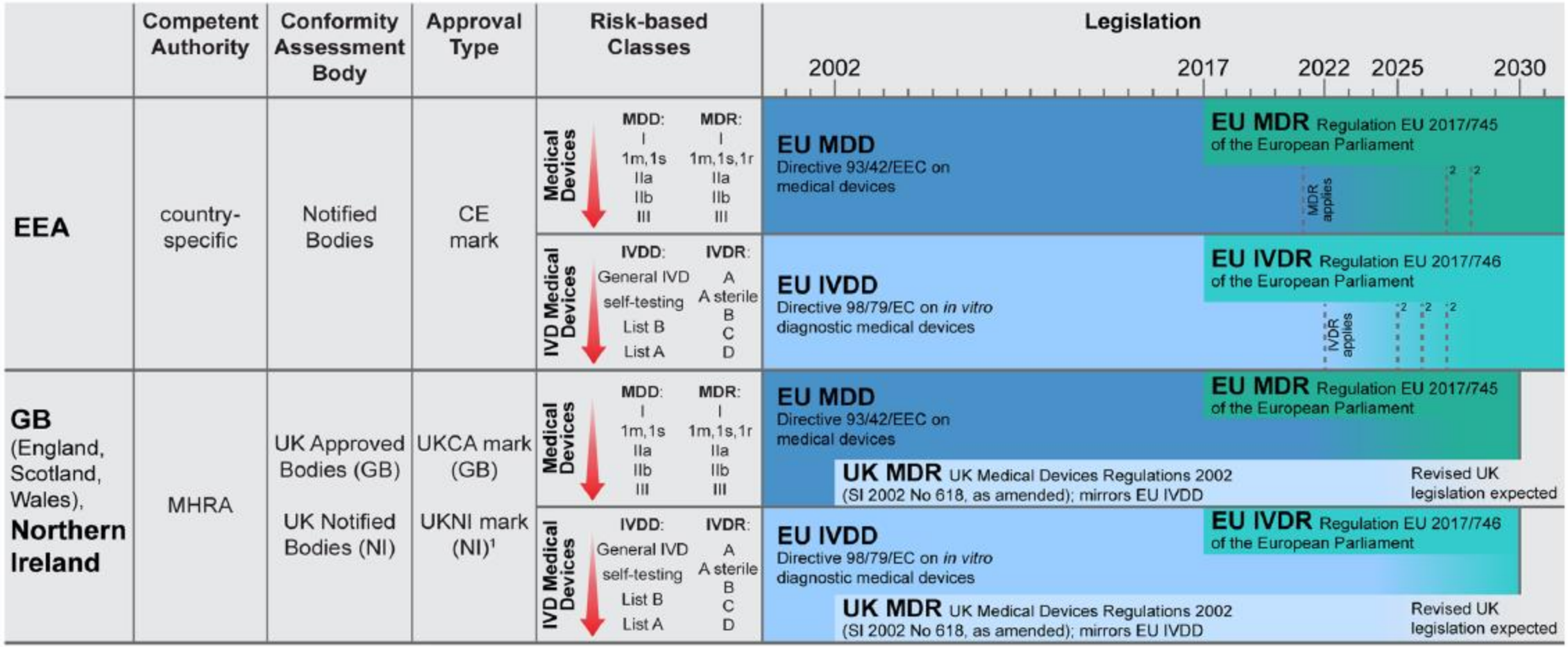


Fig. 3 Trust Barriers and Facilitators for the Use of Artificial intelligence-based Medical Devices in Cardiovascular Care



[1] UKNI marking can only be applied in combination with CE-marking.
[2] See legend for timeline details.