THE AI ACT
&
ITS IMPLEMENTATION IN BIOMEDICINE AND HEALTH

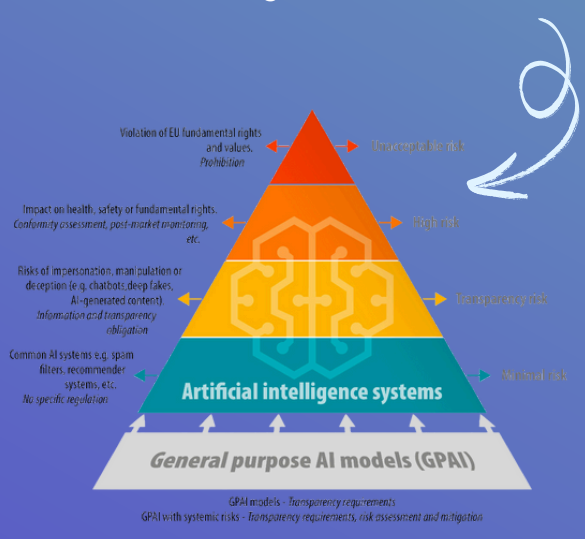
1. THE AI ACT GENERAL FRAMEWORK

The AI Act (Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence) is the **first horizontal act** laying down the EU legal framework on artificial intelligence (AI). The AI act Introduces uniform rules across the EU on the **development, production, marketing and use** of AI systems within the EU single market in respect of the values protected and promoted by the EU

Remember

The AI Act is a EU Regulation. It means that the AI Act is a legal act producing direct effects for all EU Member States and immediately binding for the EU citizens

The AI Act adopts the so called **risk-based approach**. This means that the provisions of the AI Act become increasingly stricter in proportion to the risks that AI systems may pose to people's health, safety, and fundamental rights. This regulatory approach is exemplified by the "**risk pyramid**", illustrating the different categories of risks posed by AI systems under the AI Act



The possible risks posed by AI are classified in:

1. **Unacceptable risk** (**art. 5**): AI practices that violate EU fundamental rights and values. The use of these systems is prohibited (manipulative techniques, social scoring, real-time biometric identification, etc.);
2. **High-risk** (**art. 6**): AI systems that have an impact on people's health, safety and fundamental rights (Annex I and Annex III). These systems can be used if complying with specific requirements and obligations and must undergo a conformity assessment procedure;
3. **Transparency risk** (**art. 50**): AI systems that when interacting with natural persons entail risk of impersonation, manipulation or deception. These systems can be used if complying with specific information and transparency obligations (chatbot, deep fakes, AI generated contents);
4. **Minimal risk** (**art. 95**): AI systems that do not pose significant risks and do not fall within the other classifications (spam filters, etc.). There is not a specific regulation for these AI systems (possible adoption of codes of conduct)

The AI Act regulates also **General purpose AI models** (**GPAI**), providing different rules when they may pose systemic risks. **GPAI models with systemic risks** have to fulfill transparency requirements and undergo risk assessment and mitigation procedures, while GPAI models have to comply only with specific transparency requirements. When a GPAI model is used as part of an high risk system or may pose any of the risk categories identified by the AI Act, it must comply also with the other applicable requirements.

The AI Act introduce measures to support **innovation** and foster **research** in the AI field. It provides rules for the creation of **regulatory sandboxes** for the development and testing of innovative AI systems under the supervision of competent authorities for a limited time, based on an agreed plan.
The AI Act also sets out rules for the **real-world testing** of AI systems

Member States will have to appoint **competent authorities** and create a **European committee for artificial intelligence** that will oversee the application and implementation of the Regulation. Additionally, the AI Act introduces **administrative fines** for non-compliance with its provisions

THE AI ACT DEFINITIONS

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;

General-purpose AI model means an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market

Provider means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;

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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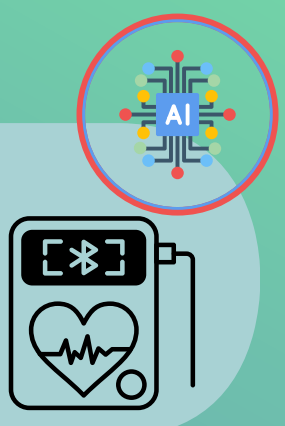
2. THE AI ACT IMPLEMENTATION IN MEDICINE



The AI Act regulates both the development and the use of AI in medicine.
More precisely, it applies when:

- AI is a component of a **medical device** or **medical device itself** (Article 6(1), Annex I)
- AI is used for **assessing eligibility for healthcare services** (Article 6(2), Annex III)
- AI is used for **assessing health emergencies** (Article 6(2), Annex III)
- AI poses particular **transparency issues** (Article 50)
- **GPAI** (Articles 51-55)

In most situations, AI systems developed and used in the medical field are considered **high risk ones**.
This means they must comply with specific requirements and obligations, ensuring:

- **Risk management system** (identification, evaluation, mitigation and management of prospected risks)
- **Data governance** (data quality and relevance, representativeness for intended use, lack of errors and bias, complete dataset, collection methods, identification of any shortcomings in the dataset provided)
- **Technical documentation**
- **Logging and relevant event recording**
- **Transparency** (information on use, capabilities and limitations, output interpretation and information on logical processes)
- **Human oversight** (human control; automation bias; ability to overrule AI decision and 'stop button')
- **Accuracy, robustness and cybersecurity**

Providers obligations:

- AI system compliance with AI Act requirements
- The quality of AI (quality system under art. 17)
- Keep relevant documentation and logs
- The systems undergoes the relevant conformity assessment procedure stated by the AI Act

Deployers obligations:

- Take proper technical and organizational measures
- Assign human oversight tasks to natural persons
- If possible, control data input
- Monitoring AI functioning and reporting significant and serious events to competent authorities
- Inform natural persons that they are subject to the use of high-risk system for decision-making purposes

AI systems developed and used in the medical field may also be classified as posing **transparency risk** and **GPAI**

GPAI in medicine:

- Technical documentation with information on system specifications, limits and capabilities;
- GPAI models with systemic risk: risk assessment and mitigation measures and technical documentation

AI with transparency risks in medicine (i.e. chatbot which are not medical devices)

- 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

Providers and deployers of AI systems in medicine 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. They have to take into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used (**art. 4**)

Some of the AI Act provisions may be applied to both **healthcare facilities** and **healthcare professionals** due to the broad definition of deployer.
According to art. 3 of the AI Act, a deployer may be a natural person or a legal one using an AI system during professional activities.
Healthcare facilities may be AI providers when developing AI-based medical devices in-house

The provisions of the AI Act are not the only rules that must be complied with in the development and use of AI systems in medicine.
Remember, you still must comply with the **other relevant EU Regulations** (GDPR, Data Act, Data Governance Act, Digital Markets Act, Digital Services Act, the European Health Data Space Regulation, etc.).
The legal framework of the AI Act may also be complemented by **national regulatory measures** adopted by Member States, within the scope of their competences

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