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Artificial Intelligence Act

About the regulation of Artificial Intelligence

2024

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MAKING AN IMPACT THAT MATTERS since 1845

Context and objectives of the proposal

Proposal published by the European Commission lays down a legislative framework to address artificial intelligence (AI) in the future to stimulate innovation and mitigate risks.

What is it about?

1. Transparent promotion of European values, emphasizing the **ethical use** of artificial intelligence.
2. Validation of the **quality** of the AI system when defining processes and roles, as well as during the entire life cycle.
3. Promoting cooperation between EU member states and a **level playing field**, as well as protecting the fundamental rights of EU citizens in the age of artificial intelligence.

What is the purpose?

- Ensuring that AI systems marketed and used in the EU are safe and respect existing legislation on fundamental rights and EU values. Non-compliance can mean an administrative fine of up to EUR 35 million!
- Creating legal certainty to promote investments in artificial intelligence and innovation involving artificial intelligence.
- Improving governance and effective enforcement of existing legislation on fundamental rights and security requirements for AI systems.
- Facilitate the development of the single market for legitimate, safe and trustworthy AI applications and prevent market fragmentation.

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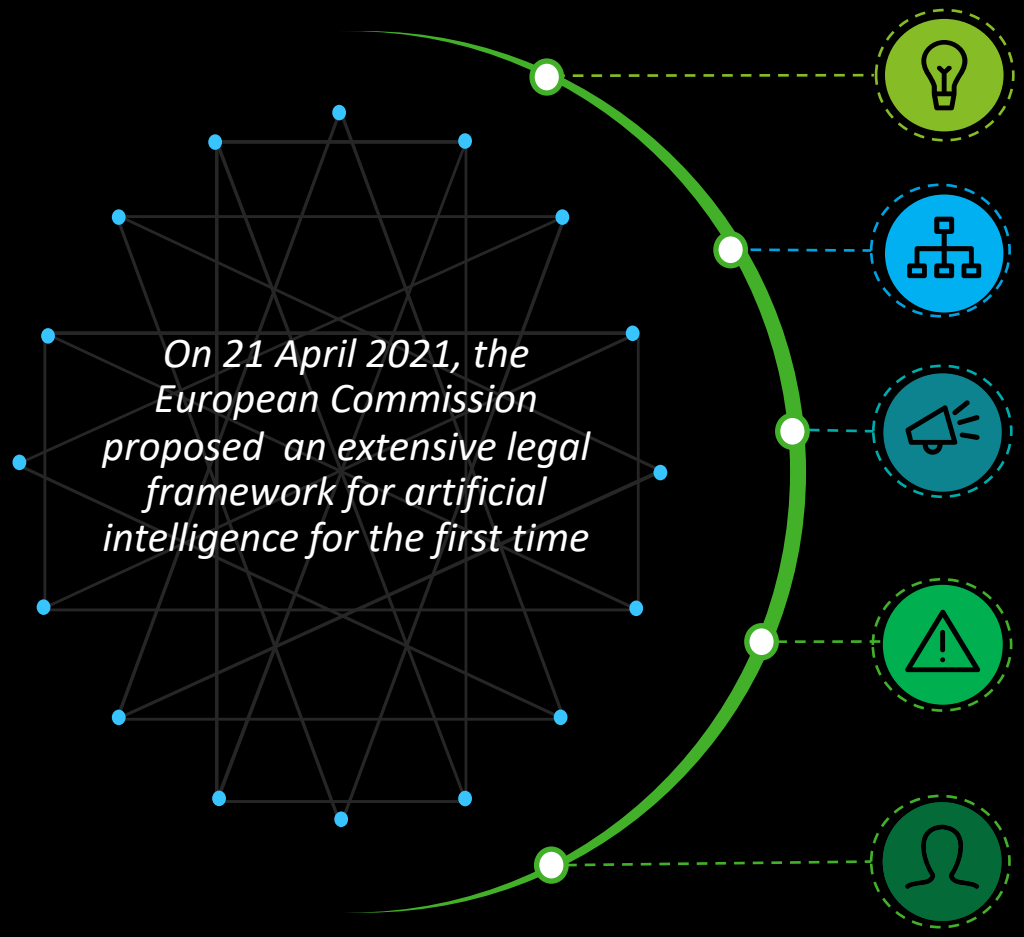
The proposal on AI Act

The proposed regulation defines harmonized rules for artificial intelligence



What is the focus?

- Using a human-centered, risk-based approach to classifying AI-based systems

Who does it apply to?

- For providers, users, importers and distributors of AI systems within the European Union*

When will it be applicable?

- From the beginning of 2027

Why is it important to focus on it?

- It may occur that the companies already use AI solutions
- The non-compliance may result in a fine of 35 **million EUR** or **7%**-of the company's total worldwide annual turnover for the preceding financial year

What can we do?

- Raise awareness of the affected parties
- Preparation and developing competences within the organisation

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Scope of the regulation

The Regulation applies to:

Providers/Importers/Distributors provisioning AI within the EU regardless of whether these service providers are established in the EU or in a third country

Providers and users located in a third country but where the output produced by the AI system is used in the Union

Users of AI systems within the EU

Entities out of scope

a) Public authorities in a third country or international organizations using AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States

b) Military institutions

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Legal definition of AI

‘**artificial intelligence system**’ (AI system) means machine-based system 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 when trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable to competently perform 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. This does not cover AI models that are used before release on the market for research, development and prototyping activities

‚**general-purpose AI system**’ means an AI system which is based on a general-purpose AI model , that has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems

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The classification of artificial intelligence systems

The proposal uses a risk-based approach to differentiate between four types of AI systems based on their potential for hazards and risk.

1 - Unacceptable Risk AI Systems

The following AI practices are prohibited:

- Manipulation of human behavior, opinions and decisions
- Classification of people based on their social behavior
- Real-time remote biometric identification (except for certain exceptions)

2 - High Risk AI Systems

High-risk AI systems are defined in the regulation as:

- Products subject to EU product safety regulations
- A list of stand-alone high-risk AI systems identified in the proposal, such as AI systems that assess individuals' creditworthiness or are used in recruitment.

3 - AI with specific transparency obligations

Some systems (such as chatbots) can deceive users who may think they are talking to a natural person. In those cases, the regulation only lays down transparency requirements to ensure that the person concerned is aware that they are communicating with an AI application on the other side.

4 - Minimal or no Risk AI Systems

Systems with minimal risk to humans are permitted without restriction, such as capacity forecasting, production planning, etc.

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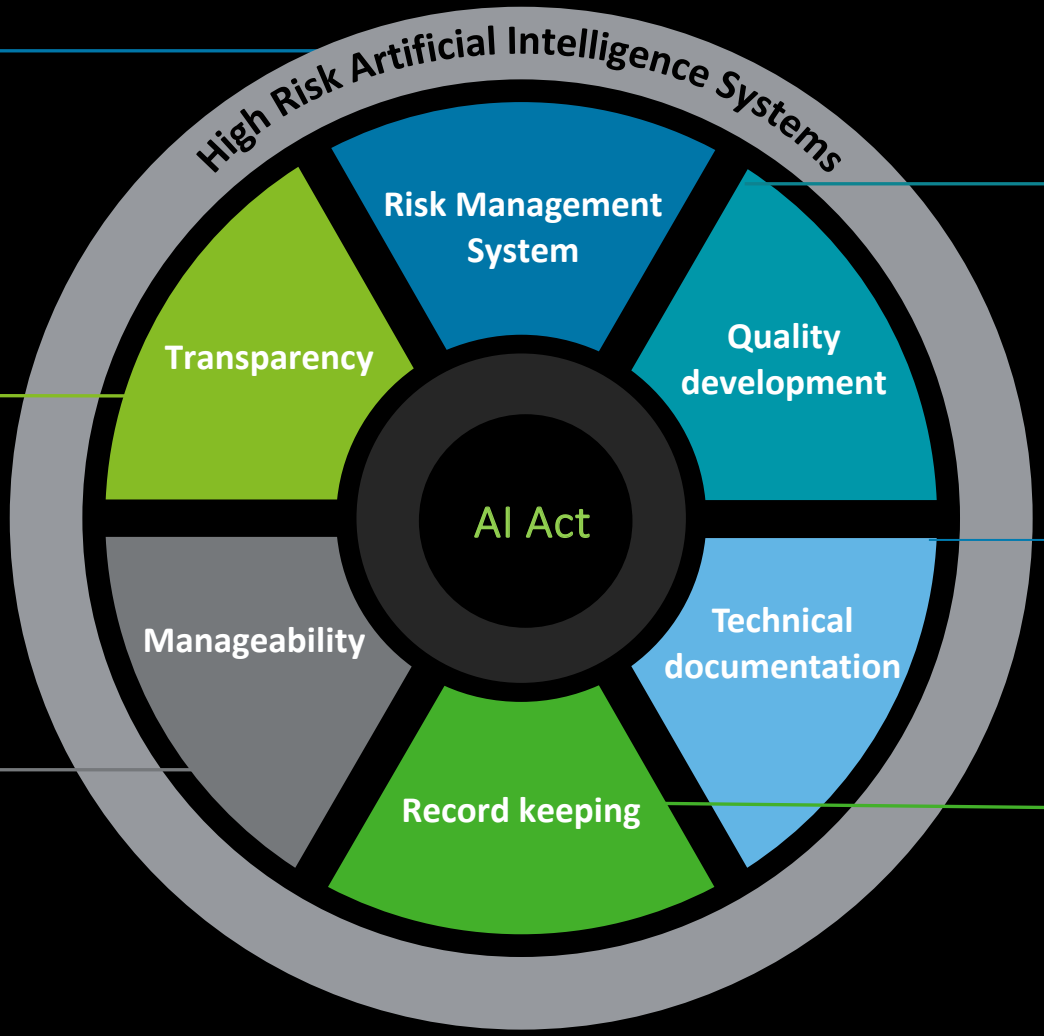
High Risk Artificial Intelligence Systems

High-risk AI systems must meet the following requirements:

Designed and developed to achieve the appropriate level of accuracy, stability and cyber security for their intended purpose and perform consistently throughout their entire life cycle.

All stakeholders are able to understand how their data is used and how AI systems make decisions about it. Algorithms, attributes and correlations are open for inspection.

It shall be designed and developed in such a way that their operation is transparent enough to allow users to interpret the output of the system and use it properly



Systems using techniques involving training models with data need to be developed based on training, validation, and testing datasets that meet defined quality criteria.

The technical documentation (operation, monitoring, risk management, etc.) must be prepared and kept up-to-date before the system is placed on the market or put into operation.

Designed and developed with capabilities that enable automatic recording of events while in operation. The logging capabilities must comply with recognized standards and industry practices.

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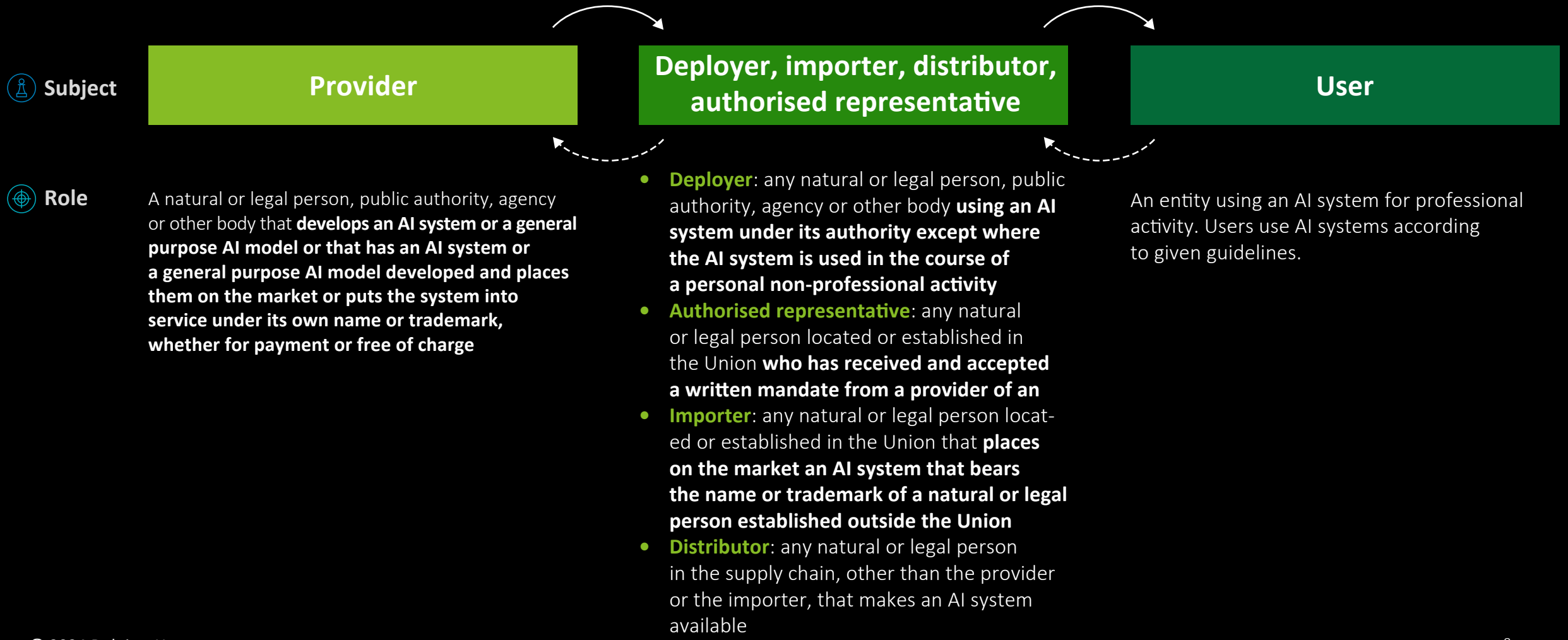
Subjects, roles and responsibilities

Stakeholders are **interconnected** and have specific performance obligations.



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Sanctions based on the recommendations of the EP of June

1

Non-compliance with the **prohibition of the AI practices**

35M€

OR 7%

of its total worldwide annual turnover for the preceding financial year, whichever is higher

2

The infringement of the other provisions of the AI Act (list)

15 M€

OR 3%

of its total worldwide annual turnover for the preceding financial year, whichever is higher

3

The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities

7,5M€

OR 1%

of its total worldwide annual turnover for the preceding financial year, whichever is higher

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Steps Towards Compliance for AI Service Providers

Determine potential risks (which potential risks (e.g. unacceptable, high or low risks)

High risk AI systems must undergo a specified conformity assessment and must repeat this step if they are substantially modified

Placing the high-risk AI system on the market or into service

Conduct a close examination of your existing assets and find out which ones use AI or qualify as AI under the new regulation

Ensure design, development and quality management system are in compliance with the AI regulation

Write a Declaration of conformity for each (high risk) AI system and affix the CE marking

A high-risk AI system requires continuous monitoring

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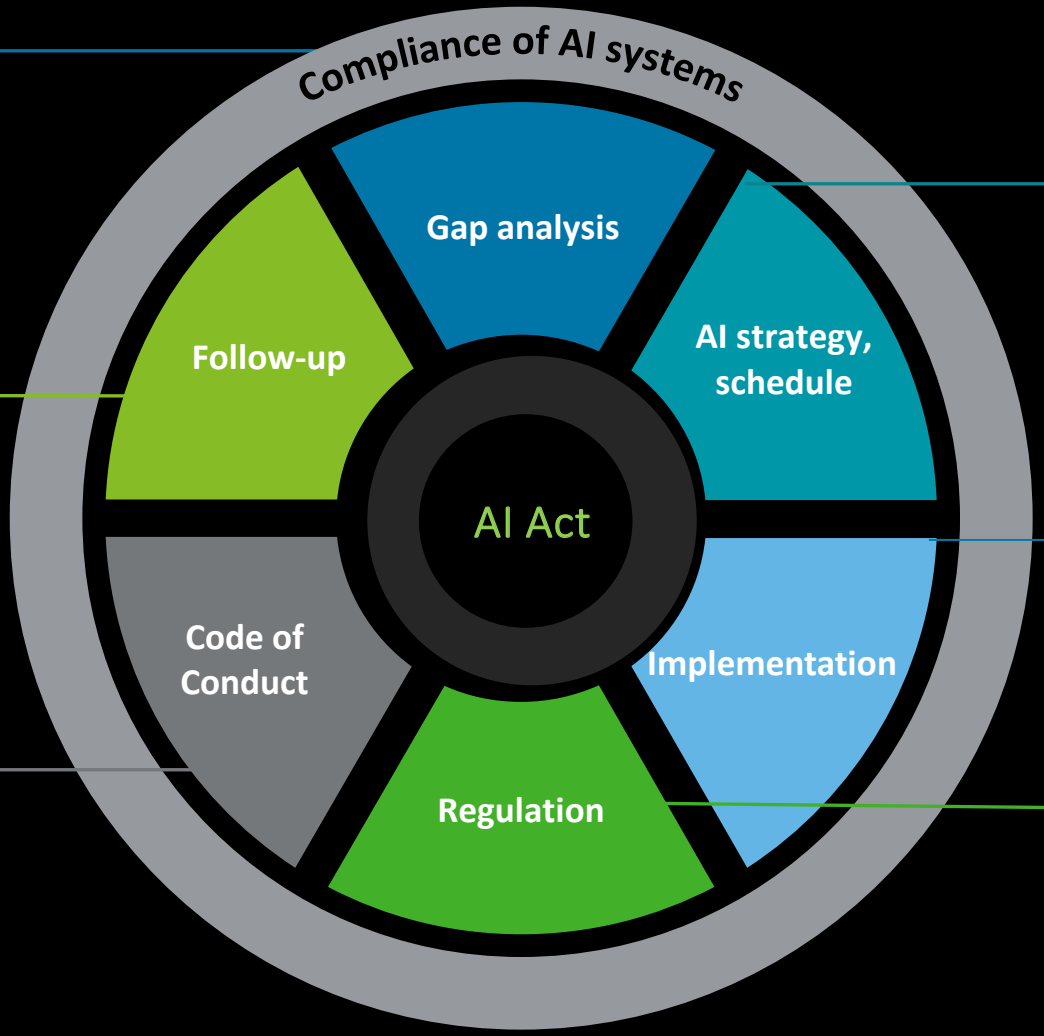
AI Act - compliance

Together with our artificial intelligence experts, technology specialists and legal consultants, we thoroughly evaluate organisational processes and solutions.

- Liabilities towards the authorities
- Inspection of unfair contractual terms
- Fundamental rights impact assessment
- Reporting serious incidents and malfunctions

Individual providers of AI systems, their representative organisations or both entities may establish codes of conduct. The purpose of a code of conduct is to promote compliance with the obligations imposed.



We prepare an action plan to facilitate the compliance with the legislative requirements. The plan will be efficiently delivered by our implementation project team and in line with client needs.

Ensuring compliance with requirements imposed regarding high-risk AI systems

Preparing internal regulatory framework

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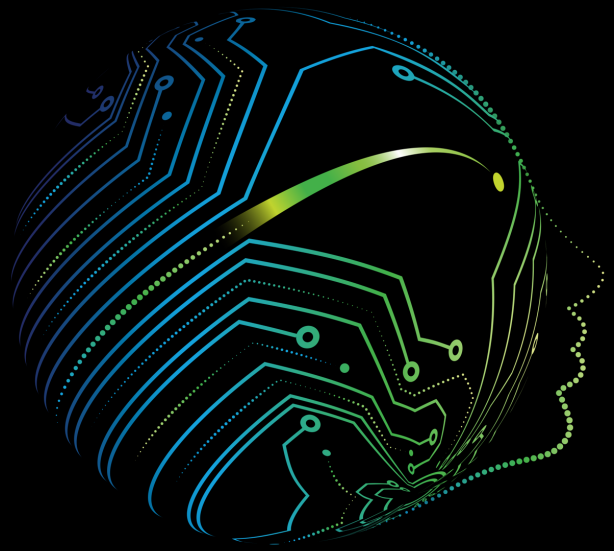
Additional services

AI Workshop

For various audiences, tailored to needs



Deloitte tools

Tools assisting legal work

Follow-up

Compliance with continuous legal obligations

Liability

- Non-contractual liability based on fault - representation in proceedings
- Liability for defective products - representation in proceedings

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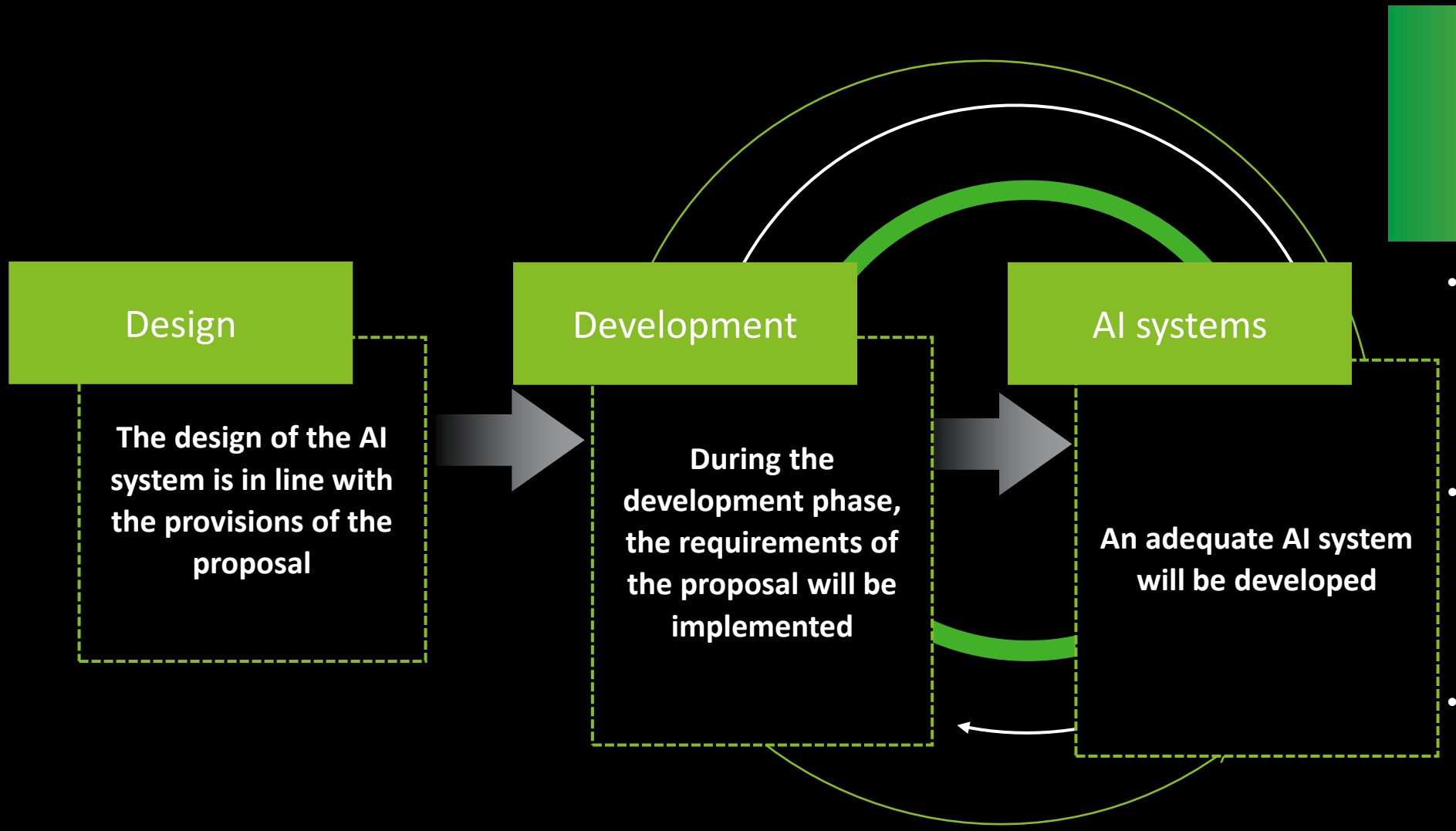
Why is it recommended start preparing now?



Legal compliance

- By the time of the entry into force of the Regulation and the end of the preparation period, a legally compliant AI system will be in place
- There is no need to re-examine and redesign the already developed, established AI system in order to have a compliant solution
- Time and cost efficiency

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Are you ready?

Responsibility and ethical use

- The Act focuses on **ethical application** of AI,
- The practitioners are **accountable for** upholding stringent quality standards.

Impartiality, fairness

- The Act includes general principles of **fair & impartial** treatment of subjects (regardless of the AI application),
- In addition, **explicitly forbids** certain apps (technologies that pose a clear threat to humans, e.g. "social scoring" by governments, exploitation of children's vulnerabilities, techniques that are not consciously perceptible, are therefore banned.).

Strict control of applications

- It specifically highlights **high risk applications** and prescribes extensive disclosure accompanied by **rigorous controls** to ensure AI systems are robust & reliable.

Human oversight

- To ensure safe & secure operation of AI, the regulation demands **human oversight**, the ability to assume control or override the AI.

Transparency, supervision

- Even for **applications deemed lower risk**, the Artificial Intelligence Act demands that AI systems are sufficiently transparent , alerting subjects to processing by AI, and that they are explainable enabling their designers to **monitor them effectively**.

Protection of human rights

- The proposal is grounded in the **fundamental rights** of the citizen, guarding against exploitation of vulnerabilities, ensuring due process, defending the **rights of children**, among others.
- It **preserves privacy** by outright forbidding applications of AI for the live, remote surveillance of citizens.

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How can Deloitte help?

Preparation of GAP analysis and implementation of legal requirements

With our artificial intelligence, technological and legal experts, we evaluate organizational processes and solutions in detail and prepare an action plan to achieve legal requirements, which our implementation project team efficiently delivers with the client's needs in mind.

- Perform GAP analysis
- Preparation of compliance action plan
- Implementation support
- Introduction of controls and tools
- Preparation of policies, guidelines and operational procedures

Risk analysis

Innovative risk management services created by organizational digitization, which are typically valid for the entire data and system life cycle.

- Development of a methodology for risk assessment and management
- Preparation of risk analysis
- Identify new risks
- Action plan development for risk assessment
- Supporting the implementation of risk management actions

Artificial intelligence consulting

Robotization and artificial intelligence offer new opportunities for transforming business processes. We support our clients to develop and apply the right AI strategy.

- Development of AI strategy and roadmap Preparing
- Development of processes for Data governance and Data management
- Quality assurance of an AI implementation project
- System development and integration
- Implementation of emerging technologies: 5G, IoT, Cloud

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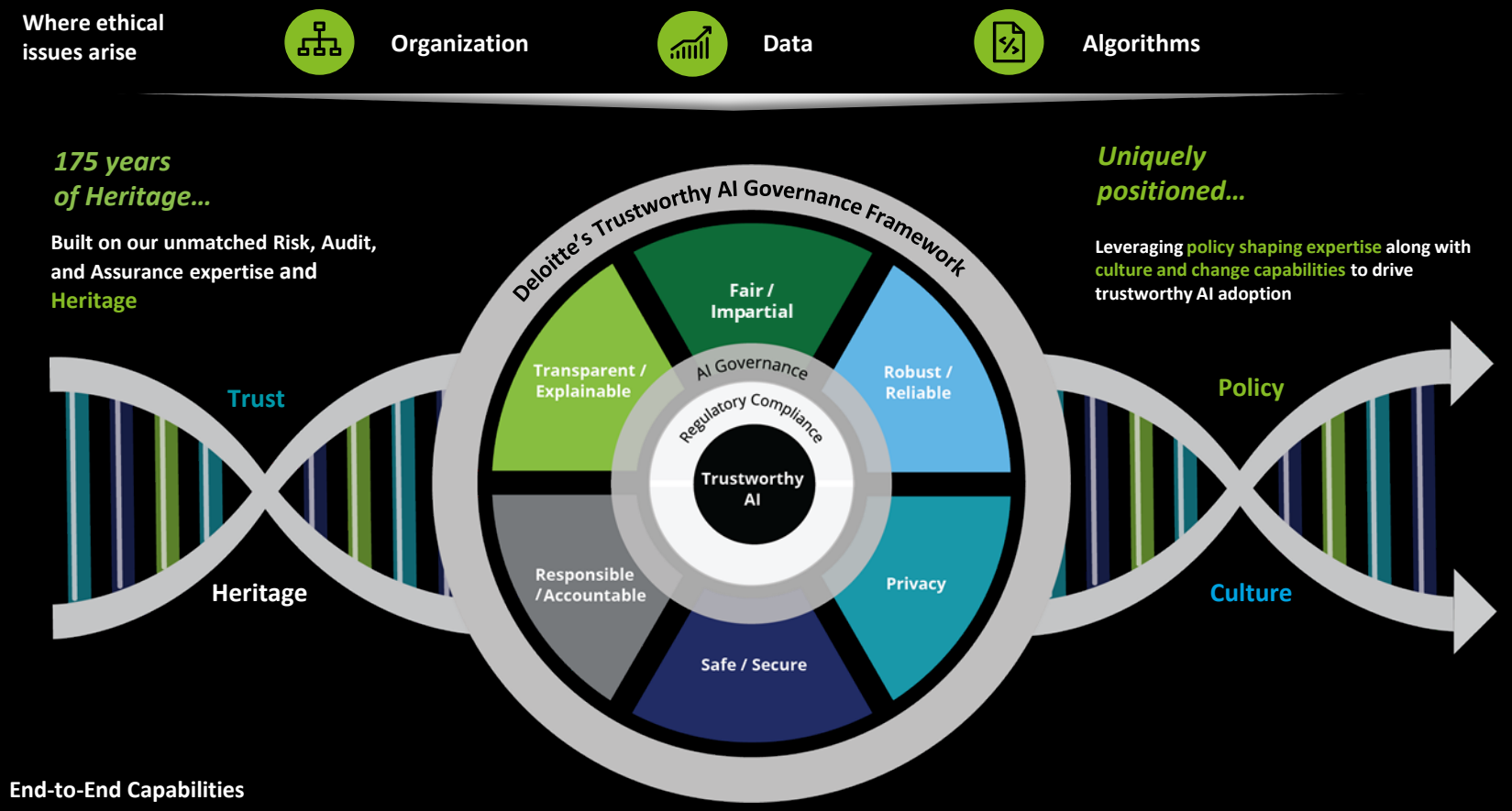
Deloitte's Trustworthy AI™ - Our Market Leading AI Governance Framework

Rooted in our Risk, Audit and Assurance heritage, Trustworthy AI™ helps responsibly harness the power of AI for the benefit of shareholders, our clients and society at large



Benefits of Trustworthy AI™

Increased brand equity and trust leading to **new customers** and **employee retention**

Increased likelihood that customers **opt in** to share their data creating a **valuable dataset**

Increased revenue / reduced costs through more **accurate decision making** due to better data sources

Reduced cost from legal and remediation activities

Positive impact on society due to increased equality (e.g., lower carbon admissions from ridesharing)

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