

# Global Gateways: Navigating the EU AI Act's Implications for Non-EU AI System Providers

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## 10. Global Impact: The EU AI Act's influence beyond Europe.

### 10.1 Setting Global Standards

*How the EU AI Act could serve as a model for global AI regulation.*

### 10.2 International Cooperation

*Encouraging international dialogue and cooperation on AI governance.*

### 10.3 Impact on Global Market Access

*The Act's implications for non-EU AI system providers.*

### 10.4 Challenges and Opportunities

*Balancing innovation with ethical and safety standards on a global scale.*

## Introduction

This is the third article in our series about Global Impact of the EU AI Act. Previous articles in this series include [Setting Global Standards](#) with Dr. Derek Warden, and closely followed by [International Cooperation](#) with Prof. Dr. Ingrid Vasiliu-Feltes.

As always, we start at step one: **What is the EU AI Act?** The EU AI Act is a landmark regulation designed to govern AI systems, ensuring safety, compliance, and innovation across the European Union.



## Implications for Non-EU AI System Providers

The EU AI Act carries significant implications for non-EU AI system providers seeking to access the European market. Despite being headquartered outside the EU, these providers must comply with the Act's stringent provisions if their AI systems are to be used within the Union (see additional clarification in **Tables 1** and **2**). This extraterritorial reach underscores the Act's comprehensive regulatory framework, which applies uniformly to all AI systems deployed within EU borders, regardless of their origin.

**Table 1:** Ways in which Non-EU AI system providers are subject to the EU AI Act (Articles 2, 22, and 54)

Method	Explanation
<b>Market Placement</b>	The Act applies to providers placing AI systems or general-purpose AI models on the EU market, regardless of their location. This means any non-EU provider selling or deploying AI systems in the EU must comply with the Act.
<b>Output Usage</b>	If the output of an AI system developed by a non-EU provider is used within the EU, the provider must adhere to the Act's requirements. This ensures that AI systems impacting EU citizens or businesses meet safety and transparency standards.
<b>Authorized Representatives</b>	Non-EU providers must appoint an authorized representative in the EU. This representative is responsible for ensuring compliance with the Act and acts as a liaison with EU authorities.
<b>High-Risk AI Systems</b>	Providers of high-risk AI systems must comply with specific obligations, including conformity assessments and maintaining technical documentation, even if they are based outside the EU.

**Table 2:** Areas of Non-EU AI system providers affected by the EU AI Act (Articles 2, 8, 16, 49, 50, 53, and 54)

Method	Explanation
<b>Data</b>	Non-EU AI system providers are in-scope of the EU AI Act concerning data when their AI systems process data that impacts the EU market. The Act mandates that AI systems, regardless of origin, comply with EU data protection laws, such as the General Data Protection Regulation (GDPR), when processing personal data of EU citizens. Providers must ensure that their systems are designed to protect data privacy and security, adhering to transparency and accountability standards. This includes maintaining technical documentation and ensuring data used for training AI models is compliant with EU regulations. The Act also emphasizes the importance of data quality and integrity, requiring providers to use high-quality datasets to minimize bias and ensure accurate AI outputs.
<b>Models</b>	For models, non-EU providers are subject to the EU AI Act if they place general-purpose AI models on the EU market or if these models are used within the EU. Providers must appoint an authorized representative in the EU to ensure compliance with the Act. They are required to maintain up-to-date technical documentation and ensure their models meet EU standards, including those related to safety and transparency. High-risk AI models must undergo conformity assessments and be registered in the EU database, ensuring they meet all applicable requirements. Providers of general-purpose AI models must also cooperate with EU authorities and may rely on codes of practice to demonstrate compliance.



<b>Users</b>	Non-EU providers are in-scope when their AI systems are used by deployers within the EU. The Act applies to deployers located in the EU, ensuring that AI systems used in the region comply with EU regulations.. Providers must ensure that their systems are designed to inform users when they are interacting with AI, maintaining transparency and accountability.. This includes marking AI-generated content and ensuring that users are aware of the AI system's capabilities and limitations. Providers must also ensure that their systems are safe and do not pose risks to users' health, safety, or fundamental rights.
<b>Consumers</b>	Regarding consumers, non-EU AI system providers are in-scope if their systems impact EU consumers. The Act ensures that AI systems entering the EU market adhere to safety, transparency, and accountability standards, protecting consumer rights. Providers must ensure that their systems are designed to prevent harm and that they comply with EU consumer protection laws. This includes conducting risk assessments and maintaining technical documentation to demonstrate compliance. Providers must also ensure that their systems are transparent, informing consumers when they are interacting with AI and ensuring that AI-generated content is clearly marked.

For non-EU AI system providers, navigating the requirements of the EU AI Act is crucial for securing market access and maintaining compliance. These requirements encompass a wide range of aspects, including safety standards, transparency measures, and ethical considerations. Failure to adhere to these provisions can hinder market entry and expose providers to regulatory penalties, impacting their reputation and bottom line.

## Real-world Examples

### Market Placement and Output Usage



A U.S.-based AI company develops a language translation AI system and sells it to businesses in the EU. The system processes data and provides translations for EU clients. Despite being developed outside the EU, the AI system's output is used within the EU, making it subject to the EU AI Act. This ensures the system complies with EU safety and transparency standards, protecting EU consumers.

### Authorized Representatives



A Canadian AI firm wants to market its facial recognition software in the EU. To comply with the EU AI Act, the firm appoints an authorized representative in Germany. This representative ensures the software meets EU regulations and acts as a liaison with EU authorities, facilitating compliance and communication.

### High-Risk AI Systems

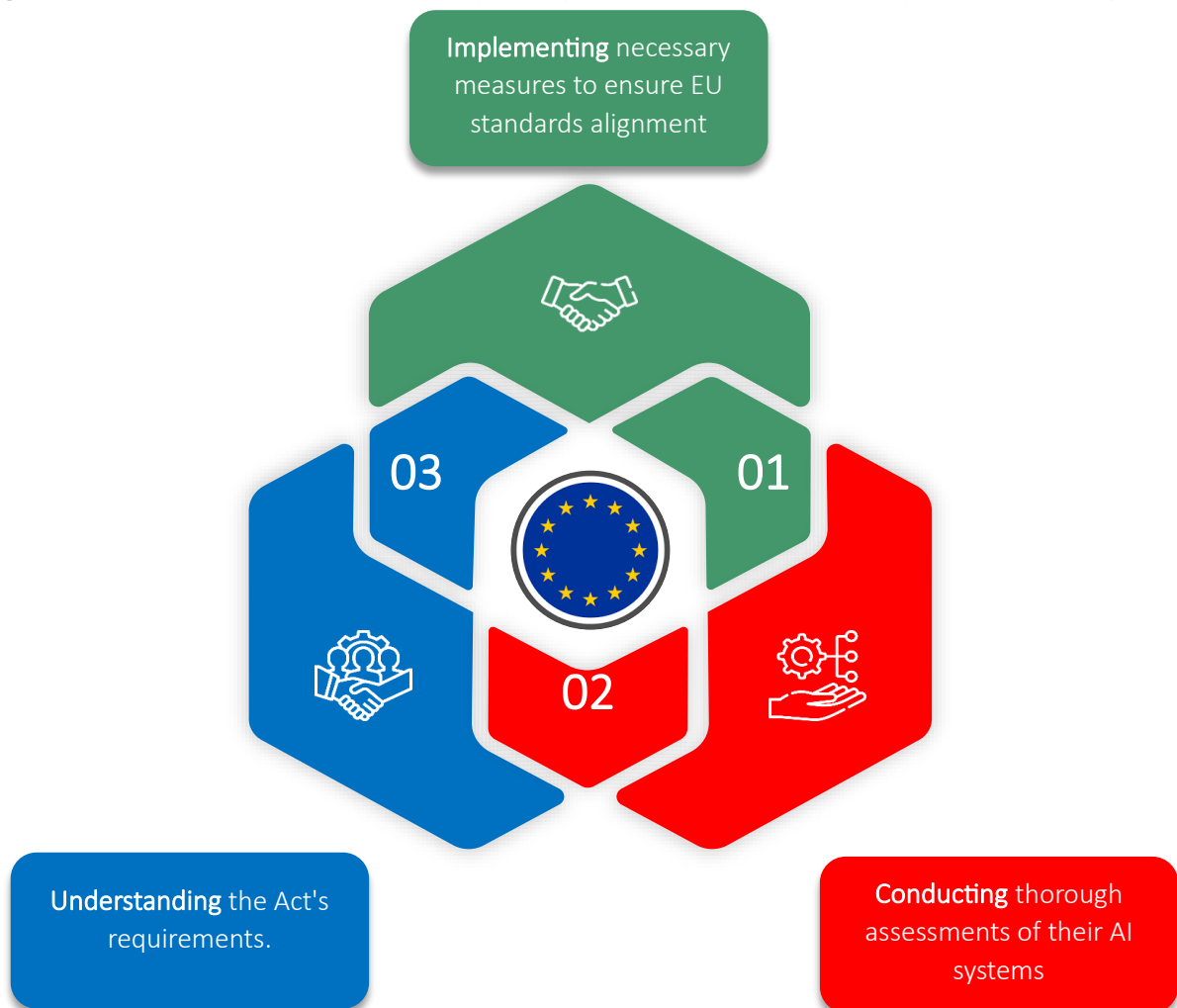


A Japanese company develops an AI system for medical diagnostics and plans to sell it in the EU. As a high-risk AI system, it must undergo conformity assessments and maintain technical documentation to comply with the EU AI Act. This ensures the system is safe and reliable for EU healthcare providers and patients.



To successfully navigate the EU AI Act's implications, non-EU AI system providers must proactively address compliance challenges. This is shown in Figure 1 below.

Figure 1: Methods to for non-EU AI system providers to address compliance challenges



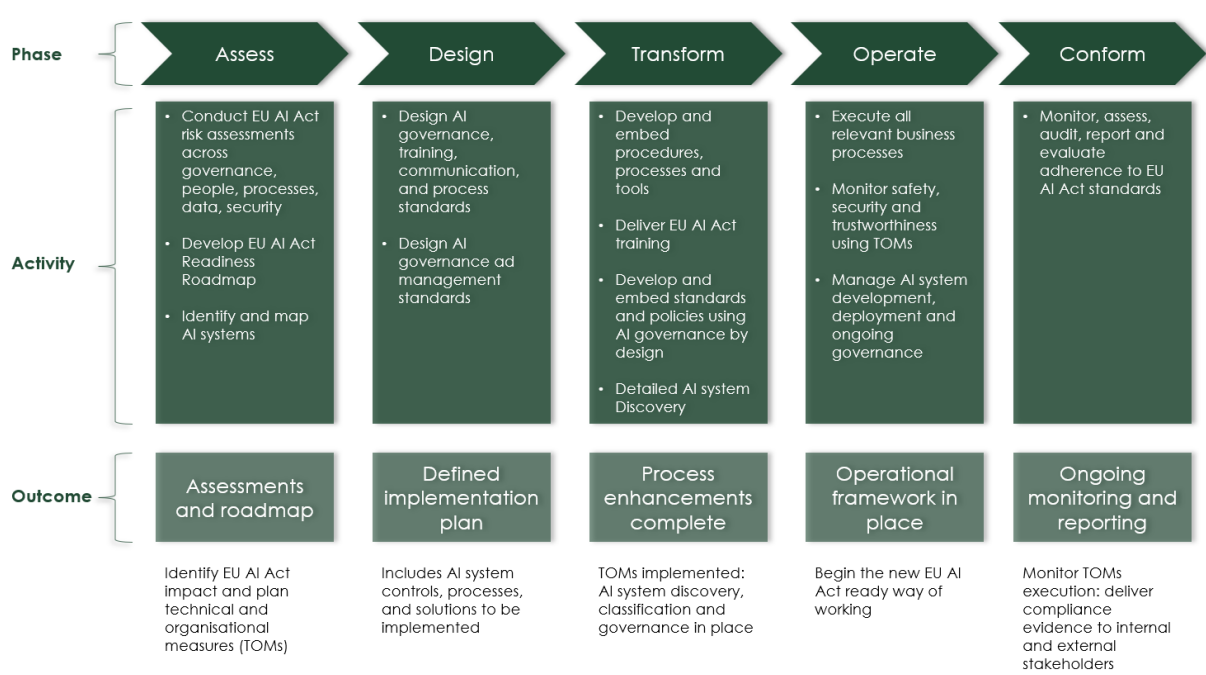
As a result of embracing regulatory compliance as a strategic priority, non-EU providers can position themselves competitively in the EU market while demonstrating their commitment to responsible AI deployment.

## Compliance Pathways for Market Access

Non-EU AI system providers seeking access to the EU market must navigate specific compliance pathways outlined in the EU AI Act. One crucial requirement is the appointment of an authorized representative within the EU, particularly for general-purpose AI models. This representative serves as a liaison between the provider and EU authorities, ensuring compliance with regulatory obligations. This forms part of the overall EU AI Act framework, as shown in **Figure 2**.



Figure 2: EU AI At Framework



For high-risk AI systems, adherence to stringent regulations is paramount. Non-EU providers must meticulously document their technical specifications and undergo thorough conformity assessments to demonstrate compliance with EU standards. These assessments serve to verify the safety, transparency, and accountability of AI systems before they are placed on the market or put into service within the EU. As shown in **Figure 3**, this falls under the Assessment pathway within Figure 2’s EU AI Act Framework.

Figure 3: EU AI At Framework Pathway



Strict adherence to compliance pathways, non-EU AI system providers can effectively navigate the regulatory landscape of the EU AI Act and secure market access. Compliance not only enables access to the lucrative EU market but also fosters trust among consumers and regulators, enhancing the provider's reputation and competitiveness in the global AI landscape.



Thus, investing in compliance measures is essential for non-EU providers aiming to capitalize on opportunities within the EU while ensuring responsible AI deployment.

## Strategic Considerations for Non-EU Providers

Non-EU AI system providers face strategic considerations when aiming to comply with the EU AI Act and access the EU market (as see in **Table 3**). Adjustments in AI system design, development processes, and data governance practices may be necessary to align with the Act's stringent requirements. This includes incorporating safety, transparency, and accountability measures into the design phase and implementing robust data governance frameworks to ensure compliance with EU data protection regulations.

**Table 3:** Key questions on strategic considerations for non-EU AI system providers (Articles 2, 22, 54, and 57)

Question	Answer
<b>What are the key strategic considerations faced?</b>	Non-EU AI system providers face the strategic challenge of appointing an authorized representative within the EU to comply with the EU AI Act. This representative is essential for managing regulatory obligations and ensuring effective communication with EU authorities. The regulation applies to providers placing AI systems on the EU market, regardless of their location, emphasizing the need for a local presence to navigate compliance requirements effectively.
<b>How do these affect non-EU AI system providers?</b>	The requirement to appoint an authorized representative and comply with EU regulations can significantly increase operational costs and complexity for non-EU providers. They must establish a presence in the EU and ensure their AI systems meet stringent compliance standards, which may involve substantial modifications to existing systems. This can be particularly challenging for smaller companies with limited resources.
<b>How can these considerations be overcome?</b>	To overcome these challenges, non-EU providers can collaborate with local legal experts and compliance consultants to navigate EU regulations effectively. Appointing a competent authorized representative is crucial, as they will handle compliance tasks and facilitate communication with EU authorities. Additionally, leveraging AI regulatory sandboxes can provide a controlled environment to test and refine AI systems before market entry.
<b>Why is responsible for ensuring these are addressed?</b>	The responsibility for appointing an authorized representative and ensuring compliance with the EU AI Act lies with the non-EU providers. The authorized representative acts on behalf of the provider to fulfill regulatory obligations, ensuring that the AI systems meet the necessary standards and facilitating communication with EU authorities.
<b>Why are these strategic considerations important?</b>	These measures are vital to ensure that AI systems entering the EU market adhere to safety, transparency, and accountability standards. By complying with these regulations, non-EU providers help protect consumers and maintain trust in AI technologies. This is crucial for fostering innovation and ensuring that AI systems contribute positively to society while minimizing potential risks.

Early compliance efforts offer significant benefits for non-EU providers. Providers that proactively adapt their AI systems and practices to meet EU standards can gain a competitive edge in the EU market. Early compliance demonstrates a commitment to regulatory compliance and responsible AI deployment, which can enhance trust among consumers and regulators.





Additionally, it allows providers to establish themselves as leaders in ethical AI practices, positioning them favourably against competitors who may lag behind in compliance efforts.

Furthermore, early engagement with EU regulatory authorities (see **Case Study: Ireland** for examples) and seeking guidance from legal experts specializing in AI regulation can help non-EU providers navigate the complexities of compliance more effectively (see **Table 4**). As a result of embracing compliance as a strategic imperative, non-EU AI system providers can seize opportunities in the EU market while mitigating regulatory risks and fostering long-term success in the global AI landscape.

**Table 4:** EU Regulatory authorities for non-EU AI system providers (Articles 57 and 70, and Recital 162)

Question	Answer
<b>Who are the key EU Regulatory Authorities?</b>	Non-EU AI system providers must navigate a complex regulatory landscape involving several key EU authorities. The European Commission plays a central role in overseeing the implementation of the EU AI Act, ensuring compliance and facilitating cooperation among Member States. The AI Office, a specialized body, is tasked with monitoring and supervising compliance, particularly for general-purpose AI models. National competent authorities in each Member State are responsible for the local implementation and enforcement of the AI Act, including market surveillance and the operation of AI regulatory sandboxes. These authorities ensure that AI systems meet the necessary safety, transparency, and accountability standards before entering the EU market. Additionally, the European Data Protection Supervisor may establish AI regulatory sandboxes for Union institutions, providing a controlled environment for testing AI systems. These authorities collectively ensure that AI systems comply with EU regulations, protecting consumer rights and fostering innovation.
<b>How can key EU Regulatory Authorities help?</b>	The key EU regulatory authorities provide essential support to non-EU AI system providers by offering guidance and resources to ensure compliance with the EU AI Act. The European Commission facilitates the establishment of AI regulatory sandboxes, which provide a controlled environment for testing and refining AI systems before market entry. These sandboxes help providers understand regulatory expectations and identify potential risks, such as those to fundamental rights, health, and safety. National competent authorities offer guidance and supervision within these sandboxes, helping providers navigate the regulatory landscape and meet compliance requirements. The AI Office plays a crucial role in monitoring compliance, offering a centralized point of contact for providers to address regulatory concerns. In collaborating with these authorities, non-EU providers can effectively align their AI systems with EU standards, ensuring a smoother market entry and fostering consumer trust in their technologies.



## Case Study: Ireland

On Tuesday, 4 March 2025, the government approved a recommendation from Minister for Enterprise, Tourism and Employment, Peter Burke, that Ireland adopt a distributed model of implementation of the EU AI Act. This approach will build on the deep knowledge and expertise of the established sectoral regulators. The government approved the designation of an initial list of eight public bodies as competent authorities, responsible for implementing and enforcing the Act within their respective sectors. These authorities are:

- Central Bank of Ireland
- Commission for Communications Regulation
- Commission for Railway Regulation
- Competition and Consumer Protection Commission
- Data Protection Commission
- Health and Safety Authority
- Health Products Regulatory Authority
- Marine Survey Office of the Department of Transport

Additional authorities, and a lead regulator who will coordinate enforcement of the Act and provide a number of centralised functions, will be designated by a future government decision to ensure comprehensive implementation of the Act.



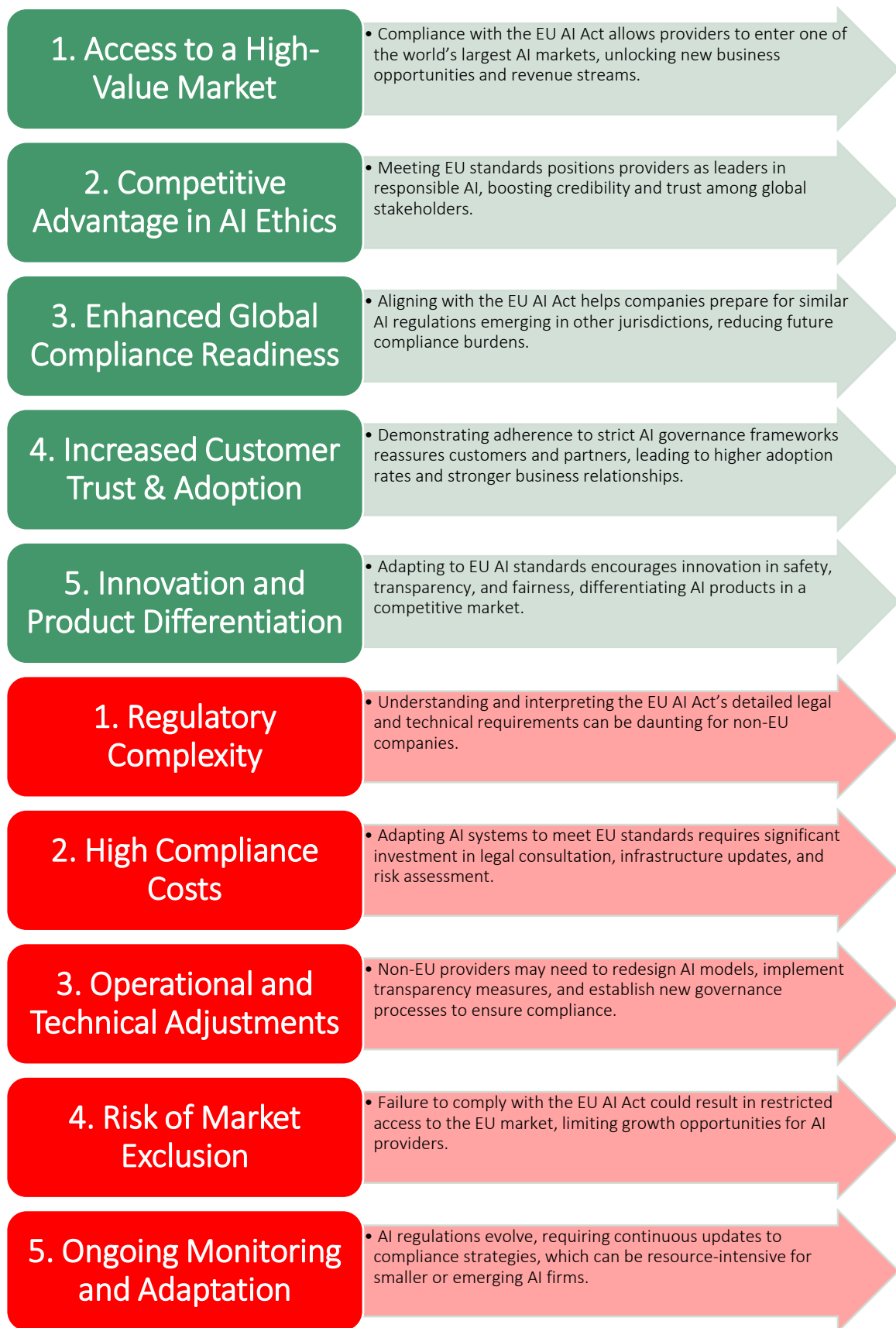
## Challenges and Opportunities

Non-EU AI system providers face challenges in navigating the complexities and costs associated with complying with the EU AI Act. The Act's intricate regulatory framework and compliance requirements may pose logistical and financial hurdles for non-EU entities. However, compliance also presents significant opportunities. Access to the large and lucrative EU market can drive growth and expansion opportunities for non-EU providers. Moreover, by embracing compliance, providers can position themselves as leaders in global AI safety and ethics standards, enhancing their reputation and competitive advantage in the rapidly evolving AI landscape. Thus, while compliance may present challenges, it also opens doors to substantial opportunities for non-EU AI system providers.





Figure 4: Opportunities and challenges



## Conclusion

In conclusion, the EU AI Act stands as a pivotal regulatory framework with profound implications for non-EU AI system providers eyeing market entry into the EU. Its influence extends beyond the EU borders, shaping global AI practices and standards. Non-EU providers must recognize the Act's significance and proactively engage with its requirements to secure successful market access. Despite the challenges posed by compliance, the Act offers substantial opportunities for growth and leadership in AI safety and ethics standards. By embracing the Act's provisions, non-EU providers can establish themselves as trusted partners in the EU market and contribute to the advancement of responsible AI deployment worldwide.



## Glossary

**Act or EU AI Act:** European Union Artificial Intelligence Act

**AI:** Artificial Intelligence

**Board:** European Union Artificial Intelligence Board

**EU:** European Union

**SME:** Small and Medium-Sized Enterprise

## How can we help?



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At AI & Partners, we’re here to help you navigate the complexities of the EU AI Act, so you can focus on what matters—using AI to grow your business. We specialize in guiding companies through compliance with tailored solutions that fit your needs. Why us? Because we combine deep AI expertise with practical, actionable strategies to ensure you stay compliant and responsible, without losing sight of your goals. With our support, you get AI you can trust—safe, accountable, and aligned with the law.

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