

SANDBOXING THE AI ACT

Testing the AI Act proposal
with Europe's future
unicorns



DIGITALEUROPE



FOREWORD

In our manifesto for the current legislative term, A stronger digital Europe, we emphasised the need for agile and mission-based policies. We stressed the importance of clear policy goals, agile policy-making processes, and multi-stakeholder engagement through regulatory sandboxing. The outcomes presented in this report align with our commitment.

I am delighted to present this report from our pre-regulatory sandboxing initiative, which aimed to evaluate the proposed AI Act and its potential implications for European start-ups and SMEs.

In our manifesto for the current legislative term, *A stronger digital Europe*, we emphasised the need for agile and mission-based policies. We stressed the importance of clear policy goals, agile policy-making processes, and multi-stakeholder engagement through regulatory sandboxing. The outcomes presented in this report align with our commitment.

Participants in the sandbox appear genuinely committed and positive to the need for AI regulation and appreciate the clarity of rules and not least the need for applicable standards in the market. The main worries are a slow-down of European innovation, investment and market share for EU companies and a gap in operational interpretation and understanding of risk categories. Further, liability exposure has created challenges and the cost of compliance remains a significant concern, but its full extent cannot be accurately determined at this stage.

Another notable issue highlighted is the lack of existing standards, and consequently uncertainty about what formal harmonised standards will ensure compliance. Participants also show that achieving compliance will be a time-consuming process, which for many will exceed 12 months after the finalisation of technical standards.

Considering the global nature of the AI industry, the impact of the AI Act on international competitiveness is a pressing concern. Some worry that the implementation of the AI Act may hinder their ability to work with high-risk AI models in Europe and deter international investors.

The Sandboxing exercise has revealed discrepancies in compliance distribution across EU member states. Participants perceive that countries with robust governance and regulatory systems may be better equipped to manage compliance and harmonisation.

This exercise underscores the importance of incorporating sandboxing into the fabric of the EU's better regulation principles. By engaging in agile policy-making processes, we can boost responsible AI deployment through private public collaboration, while ensuring Europe remains at the forefront.

I extend my gratitude to all the participants who contributed their insights, as well as the dedicated teams involved in organising this sandboxing initiative. Together, we can shape a future where Europe's digital landscape thrives, driving economic growth and societal benefits while upholding the highest standards of ethics and accountability.

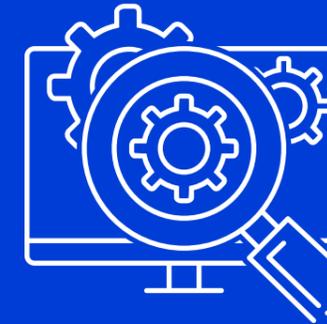


Cecilia Bonefeld-Dahl
Director General
DIGITALEUROPE



By engaging in agile policy-making processes, we can boost responsible AI deployment through private public collaboration, while ensuring Europe remains at the forefront.

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Study methodology

The findings in this report are based on in-depth interviews conducted between 2 March and 20 April 2023 with 9 European start-ups and SMEs.

All companies were selected by DIGITALEUROPE as nominees of the Future Unicorn Award, and for being organisations that build and develop artificial intelligence (AI). Participants were from 8 European countries, mostly represented by CEOs.

The full list of participants is available on the acknowledgments page.

The aim of this project was to investigate participants' compliance and market strategies with respect to the proposed AI Act, including its impact on their business and the wider business landscape more generally.

The following topics were covered:

- ▶ Familiarity with the AI Act proposal
- ▶ Familiarity with AI standards and the system of European harmonised standards
- ▶ Compliance impact
- ▶ Business impact
- ▶ Implications of the proposed AI Act for organisations

The interviews were run by an experienced Savanta moderator team, the discussion was recorded and transcribed for analysis.

Note: The quantitative data presented in this report is not representative of the target population (tech sector in the EU) due to the limited size of sample (N=9), and should therefore be treated as indicative only.

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Executive summary

This report summarises the findings from a pre-regulatory sandbox with 9 European start-ups and SMEs.

Participants in the sandbox have generally expressed cautious optimism about the need for AI regulation. However, the sandbox has highlighted numerous areas where improvements and further reflection are necessary in order for participants to be able to comply and measure the impact of the proposed AI Act on their business operations.

Notably, our AI Act sandbox has highlighted that:

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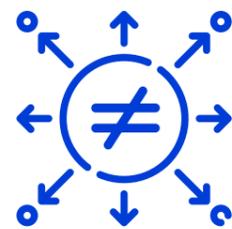
A majority (two-thirds) of participants only have **basic knowledge** of the requirements and cannot fully understand their market implications. Many participants lament a **lack of clarity** as to which **risk category** their product falls into, the **applicable technical standards**, and their **liability exposure**. The cost of compliance is expected to be the main driver of financial impact, but the full extent of this cost cannot at present be calculated.



The current **lack of existing standards and resources** for many participants to get involved in formal standardisation activities generates uncertainty as to the expected benefits that harmonised standards will bring.

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Half of participants expect compliance to take 6-12 months, while others expect **more than 12 months once all the aspects, including the applicable technical standards, are finalised**.



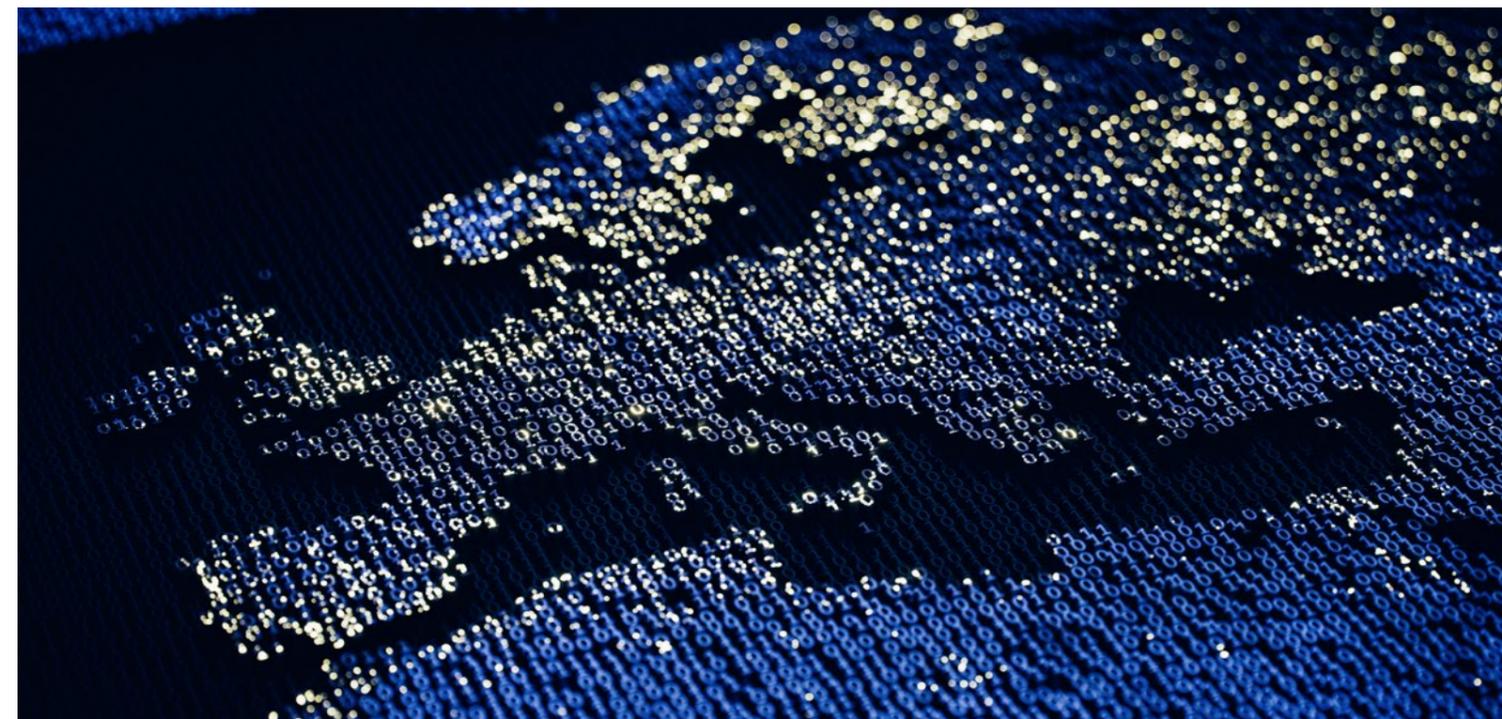
Participants expect compliance will be **unequally distributed across the EU**, generating further discrepancies between Member States with strong governance and regulatory systems, such as Germany, the Netherlands or Scandinavian countries, and the rest of Europe.

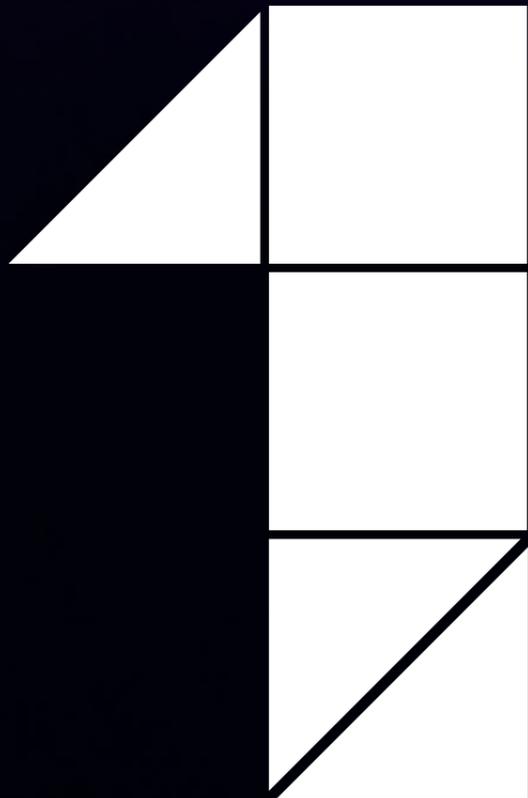


When it comes to third countries, some participants expect the AI Act to give them a competitive advantage compared to non-European providers, whilst others think this won't be the case. For them, **implementation of the AI Act is likely to make it more difficult to begin working with high-risk AI models in Europe**. These participants are particularly worried international investors will shy away from funding high-risk European AI companies, and would consider moving to other geographies where they currently operate in this scenario.

In light of these findings, we put forward six key recommendations to ensure the upcoming AI Act and its regulatory sandboxes can create the right level of compliance and competitiveness for European companies:

- 1 There should be **no regulation without a plan for investment**, or the EU risks falling behind.
- 2 The proposal needs **more clarity on scope**. This has only become more important given late discussions on general-purpose systems, which might bring more companies into scope than originally envisaged in the Commission's proposal.
- 3 The **existence of harmonised standards by the time the AI Act enters into application** will be key to provide companies with clarity as to their exact obligations and implementation strategies.
- 4 There should be a **focus on the international level** to align on standards and terminologies. For many participants the US market is key. The EU-US Trade and Technology Council is an excellent place to start.
- 5 Gradual implementation and practical support will be key for SMEs. **More funding and resources should come from the EU for compliance**, including to make sandboxes easily accessible to a wide range of businesses.
- 6 The AI Act should allow for modifications down the line – there should be a **continuous sandboxing approach**, focusing on adapting the text in the long run based on practical experience rather than purely aimed at compliance.





FAMILIARITY WITH THE AI ACT AND AI STANDARDS

1.1. Familiarity with the AI Act and its provisions for the development and use of AI

A majority of participants interviewed have only basic knowledge about the proposed AI Act. The majority – around two-thirds – sit between 'unfamiliar' and 'somewhat familiar.' Whilst they know the AI Act is being set out in time, they will have to work closely to ensure compliance. They display a rough understanding of the direction the AI Act is likely to take them in. However, there is more that needs to be done to ensure all businesses are fully aware of the potential impacts the final text may have on their operations once implemented.



There is a need for further clarification. Legislation typically wants to be sustainable through time, so a lot of the discussions are about: "What is AI, actually?" At this moment it seems like a lot classifies as AI when you read the AI Act.

Anna-Greta Tsahkna
Timbeter



It's people looking idealistically at outcomes and saying: "Somebody is responsible and we're going to put a blanket legislation in place." And they don't actually know how they're going to enforce it or how it will impact onto industry or the economic impact of what they're doing.

Nigel Toon
Graphcore

Few participants have a more detailed knowledge of the AI Act. They place themselves somewhere between 'very familiar' and 'extremely familiar.' This is driven by the nature of their AI systems and by their own evaluation of their level of compliance with the proposal. A minority are already trying to design with the AI Act in mind to mitigate future disruption to their operations and clients. In contrast, the majority are waiting for the final legal text before assessing the full extent to which they will have to comply and alter operations. There is a consensus that making changes too prematurely may result in duplication of efforts and costs.

Despite an acknowledgment that new legislation is needed to provide protection and best use of AI-powered technology, participants have signalled the AI Act is **too broad** and doesn't offer a true sense of scale in terms of how companies will approach and comply with it.

1.2. Initial perceptions about the AI Act

A key aspect mentioned by many participants is that there is a lot of **uncertainty and lack of clarity**, namely with respect to the definition of AI and classification of risk:

- ▶ The **definition of AI** is extensive and vague. This is due to the AI Act being a general regulation, and not case specific as other instances. It is not clear how and to what extent different use cases can adapt to and comply with it.
- ▶ Several participants are unclear on some of the thresholds between the different levels of risk, and are unsure what this classification means for the variety of AI-fuelled products they develop and use.

Some participants stress the possible negative impact of the AI Act on **innovation** within the EU, which can be serious given that AI is the technology the next industrial revolution will be built upon. Given the current industry aggregation movement and concerns about monopolisation of AI, they feel that the EU is at risk of missing out on AI R&D, with the result of not being able to compete and becoming completely dependent on other geopolitical entities.



There seems to be, to me, a lot of uncertainty and unclarity about what is the right tool, and how we should proceed to, in the future, identify what is potentially high risk or low risk, and what actually AI in the end is.

Martin Canter
Omina Technologies



Europe is still very focused on regulations, and is not putting the right investments into AI. This is very concerning because we're going to continue to deepen the gap and be completely dependent on US technology or Chinese technology in Europe.

Daniela Braga
Defined.ai



In addition, some participants mention uncertainty around the **enforcement** of the rules, as well as about how they will be **integrated** into current risk-management processes of AI solutions under different EU legislations. In addition, some participants operating globally are worried that complying with the AI Act, in addition to other AI-related regulations, will pose a challenge when deploying technology applications across various regions worldwide.

At the same time, many participants **acknowledge the EU's effort** in putting forward standards related to AI and, by doing so, recognising the importance of ethical AI.



The EU from the outside is often seen as a single market, but actually we're still looking at the 27 independent states often with very fragmented laws. It still is often the case that there are some bits and pieces here and there that you have to consider when doing business locally. So, from our side, from a business that is operating globally, we do appreciate first and foremost less fragmentation. Having as uniform a rule as possible is good.

Aleksander Tsuiman
Veriff

Participants appreciate the fact this **horizontal legislation** will reduce fragmentation within individual Member States, setting a level playing field within Europe and avoiding uncertainty which can be detrimental to business and investment.

Generally, participants are supportive of **sandbox exercises** and think there is a clear need to use them to ensure everyone interprets the AI Act in the same way.



1.3. Compliance with relevant standards for development and use of AI

Most participants **do not use any standards specifically for the development and use of AI**. They stress there is currently no comprehensive source to consult in relation to development and use of AI, at EU or international level.

This highlights challenges particularly for smaller companies due to lack of resources associated with building internal standards or certifications.

Many mention there are a plethora of guidelines and practices, and those interested need to do

research into all sources available to build internal standards within their company.

Four participants mention specific standards and/or information sources they use in relation to R&D of AI such as the ALTAI assessment, the AI HLEG ethics guidelines for trustworthy AI, standards for responsible AI issued by specific countries, private companies or local regulatory authorities. In addition, compliance with specific ISO standards around information security is mentioned by a few participants.

1.4. Familiarity with the system of harmonised standards and their application to the use of AI

The majority of participants interviewed are unfamiliar with the system of European harmonised standards and how it applies to the use of AI.

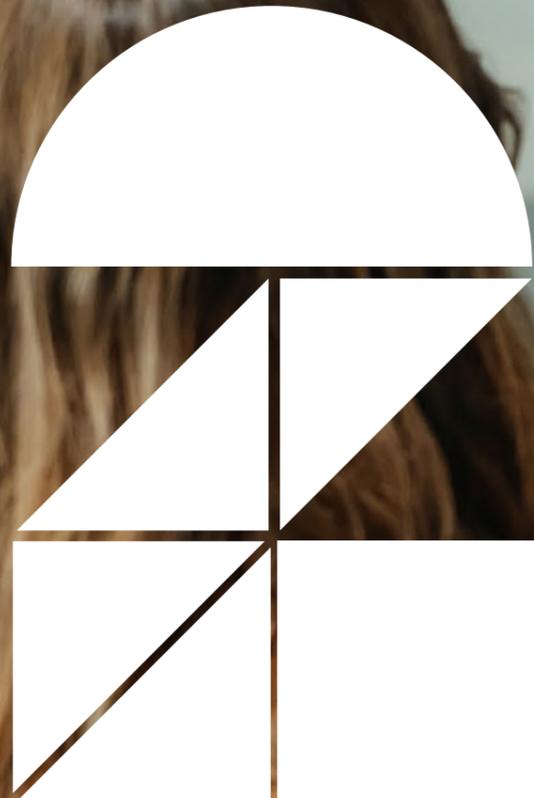
Those who are aware of harmonised standards are either heavily involved in this sector, e.g. by being part of specific industry committees or interest/working groups who share knowledge on standards, or have a solid understanding of the legislative acts thanks to their background in law or regulation.

1.5. Familiarity with the system of harmonised standards and their application to the use of AI

Participants display interest in taking part in European standards organisations to develop harmonised standards for AI. However, most participants have no or little experience of industry committees or interest/working groups

on standards, and lower capacity to influence this area as opposed to larger companies. There is work to be done to ensure **participation is user-friendly and open to all**.





COMPLIANCE IMPACT

2.1. Readiness to comply with the AI Act

The sandbox was not able to provide definitive answers as to whether participants are ready to conform with the AI Act requirements, given that the text is still not finalised. As mentioned previously, the proposal is considered vague and uncertain by some participants. It will take some time to translate the requirements of the final AI Act into specific actions and understand what processes, tools and solutions need to be implemented.

Some areas related to compliance that lack clarity are:

- ▶ Who is responsible to be compliant with what and to what extent? Namely what response is expected from companies with different roles, e.g. platform supplier vs. platform builder, and whether there will be joint responsibilities in the AI creation process.
- ▶ Where liability lies.
- ▶ What specific requirements regarding societal and environmental impact? The current requirements are seen as vague and in part driven by how customers deploy AI solutions.
- ▶ How to measure bias and what data quality requirements are.

Two participants who have more experience in internal compliance processes and certifications have a better understanding of the AI Act's key principles and are more confident in saying they are ready to comply with them.

However, views on compliance depend on the **perceived level of risk** companies think they would fit into. Those who consider their AI solutions to be minimal or limited risk have no particular fears in regards to compliance, whilst those probably classified as high risk are particularly nervous about this subject. One participant had to reassess its previous opinion that its AI solutions would not classify as high risk.

Two participants pointed out that whilst AI solutions can be designed to keep human oversight to be able to intervene, the unpredictability of AI systems will probably lead to unexpected results and/or errors. This particular rule combined with regulatory uncertainty and the risk of not being compliant might lead to a delay in AI innovation projects in Europe. One suggests it would be more suitable to focus on the companies being able to explain the results of AI models.



I think the bigger debate now is that people have different views on how to measure risk. Whether it's a risk-based approach or it's an impact-based approach. I think having some thresholds that are not in absolute terms, so to speak, in terms of risk, which the EU is looking at for the moment, is difficult because these are new technologies that we're dealing with. I don't think it's a bad method, but I'm not sure it's going to be the one that will survive in the longer run.

Mikael Munck
2021.AI



2.2. Resources required for compliance with new legal requirements of the AI Act

Companies foresee the need of assistance with **two key areas** related to compliance with the AI Act, namely:

1. **Legal services** provided by legal compliance teams/law firms; and
2. **Additional resources** to apply the new requirements into ways of working and R&D of AI applications.

Any internal resources dedicated to compliance are perceived as leading to time delays in R&D, and as having a negative impact on innovation driven by SMEs and start-ups in Europe.

One participant suggested the most important area will be technical assistance in terms of interpreting and implementing the requirements.

Two participants discussed the need for hiring people with a profile between compliance and data who will be able to decipher some of these regulations for software engineers. Some participants also foresaw the creation of middle layer companies/consulting firms who will offer certification support services.

2.3. Cost expectations for compliance with the AI Act and relevant standards

Whilst all participants agree there will be additional costs incurred from the AI Act, it is **difficult to determine** how high these will be due to the general lack of clarity associated with the final text.

Most participants expect those costs to cover **overhead costs** (e.g. quality manager of the standards, governance and risk manager) related to familiarisation with compliance processes and conducting AI conformity assessments. In addition, they expect there to be **direct financial costs** such as paying for a certification.

Again, participants suggest that the implications of additional costs will weigh heavier on SMEs and start-ups, for whom the biggest cost will not be monetary but the opportunity cost, i.e. assigning crucial company resource to compliance rather than innovation. As few participants pointed out, this may not only lead to loss of business, but to companies looking for other sources of revenue outside the EU.



There's a lot of unclarity about [costs] as well. How extensive will that be? How many resources will that cost? Strategically, for us, we know that we are in a good place to build compliant, high-risk AI solutions. But obviously, if there is a very high post-production cost to it, it might be no longer beneficial.

Anita Prinzie
Omina Technologies



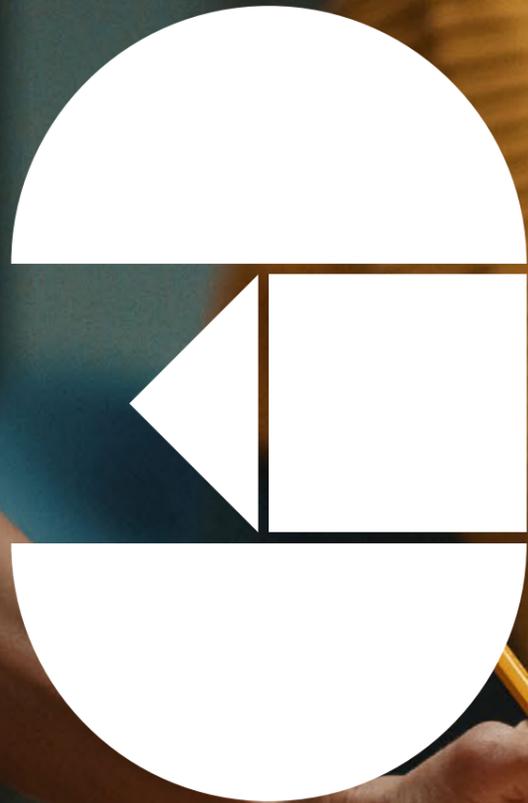
2.4. Time required for compliance with legal requirements of the AI Act

The timeframe needed to ensure compliance with the AI Act's legal requirements is **difficult to assess** as it is not clear exactly what the requirements in the final text will be and what they will entail. As seen above, most businesses only have a basic understanding of what is included in the AI Act, and there is a **lack of clarity** about key points. The expected timeframe also changes based on the perceived risk category.

Half of participants expect to be compliant within 6 and 12 months, depending on what the

exact legal requirements and finalised technical standards will be. Nevertheless, some expect the time needed to be at least 12 months by the time they will have put in place all of the changes and support that might be required.

Companies hope there to be a **lead time** before the AI Act becomes fully enforced to reflect the requirements in algorithm-building processes and future developments.



BUSINESS
IMPACT

3.1. Financial impact of the AI Act on businesses

The financial impact of the AI Act on the participants remains unclear. **Cost of compliance** is expected to be the main driver of financial impact, with some indirect costs potentially affecting supply chains and overall market distribution expected as well.

Participants anticipate different outcomes depending on their company's nature, perceived level of risk, sub-sector and products, among other factors. For example, participants who believe they will unlikely be classified as high risk view the AI Act as a **necessary cost** that may even present business opportunities in the future. They expect the AI Act to present a competitive advantage when entering into international markets. On the other hand, high-risk companies foresee **substantial costs** that could hinder their innovation potential.

What is common to all participants is the desire for the financial impact to be minimal. However, many have said that until the text is finalised and operationalised, it is difficult to determine the exact costs they would face. There is a view that being more prepared at an early point will allow businesses to manage any costs. However, the majority will wait for the final legal text before starting full-blown compliance, which may otherwise result in duplication of efforts and costs if done too early.



I think for companies who don't do it, and who have no skills, these kind of things tend to come as a last minute surprise, then you have more issues to worry about. If you start early, and you have capabilities, I think, then you are ready when the market is ready.

Antti Koskela
WithSecure

3.2. Impact of the AI Act on international competitiveness

Whilst many participants agree that compliance with the AI Act could give European companies a **competitive advantage**, some mention this might be **unequally distributed** across the EU. Some countries, particularly those with strong governance and regulatory systems, such as Germany, the Netherlands or Scandinavian countries, tend to have stronger standards on privacy or transparency. Therefore, benefits compared to other countries when it comes to the implementation of the Act will be felt there.

One participant stressed the importance for smaller companies with limited resources and companies located in less well-prepared countries to have **access to funding** to ensure they can keep

pace with the rest of the EU. This is an important consideration for maintaining a competitive landscape across the bloc.

Compliance with the AI Act can also help when looking at business opportunities outside of the EU, especially if the EU becomes a role model for other countries.

When comparisons are drawn with specific **global markets** such as the US, opinions are **divided**. Some say compliance with the AI Act will give extra points to European providers, whilst others think third countries will not take compliance with the AI Act into account in their decision-making.



Will the AI Act be pro-business and does it address actually the concerns that are also there in other jurisdictions? Usually companies, at least tech companies, want to think globally, so I think that having the AI Act as competitive as possible is essential.

Aleksander Tsuiman
Veriff

Implementation of the AI Act is likely to make it more difficult to begin working with high-risk AI models in Europe due to increased complexity and barriers. This could negatively **affect new start-ups** that may have otherwise established themselves in Europe, as they may choose to relocate their operations elsewhere. If the AI Act makes the EU a less attractive destination for high-risk AI start-ups or innovation hubs, **it may put investors off** as a result.

The decision to move away might not come from companies themselves, but from their investors as a reaction to general uncertainty around the Act and its implications for specific profiles of companies – namely, high-risk. For companies with some operations in other geographies, those are the natural place **they would relocate to in a worst-case scenario**. And whilst moving operations to other markets is not an option for many, some say it is something they have been considering.

Nevertheless, the AI Act wouldn't make well-established, low or no-risk organisations move away as they are committed to the EU and would still be subject to compliance with EU regulations if they were to keep a presence in the bloc. Moving business operations elsewhere isn't seen as a practical move. However, a few companies would consider doing so **if complying with the AI Act negatively impacted their accuracy or competitiveness**, and if moving abroad provided greater freedom to innovate thanks to a different regulatory landscape.



I've had some conversations with investors that are worried about the dampening of AI innovation on the European market, so investors are pushing us to focus first and foremost on the US market. This is also probably what we will do, we will not abandon the European market 100%, but I would probably have the US market higher on my list than, let's say, the Italian market or the Spanish market.

Jonas Andrulis
AlephAlpha





3.4. Impact of The AI Act on company's reputation and customer perception

Overall, there is an agreement that regulation is necessary to establish trust, ethical use and responsibility in AI development, and that the AI Act will be beneficial in achieving this. It may force companies to optimise, adopt a better roadmap and strategy on the AI route. On the other hand, some participants think it will **increase the cost of accessibility** on most projects, making it more expensive for companies to meet requirements and targets.

There is an expectation that **standardisation** will be a key benefit of the AI Act, making it easier for investors to understand what constitutes AI and invest accordingly. However, the current lack of existing standards and resources for many participants to get involved in formal standardisation activities continues to generate uncertainty as to the expected benefits that harmonised standards will bring.

Some participants voiced concerns about potential negative impacts of the AI Act on European companies' innovation and reputation, as well as negative impact on the general investment climate if regulations are perceived as holding back progress.

According to some participants, current uncertainty surrounding the text (both the classification of companies and how the rules will be implemented) will likely **decrease investment levels** in the short term until regulations become clear, and whether investment levels will recover or remain subdued will depend on how manageable the requirements outlined in the final Act are and how much they are perceived to stifle innovation.

Many participants agree that even though interventions and regulations are necessary, there needs to be more **careful consideration given to their implementation**.



I'm pretty sure in the coming years, there will be a vast amount of AI start-ups popping up, especially thanks to ChatGPT. And the investor side usually does not go very deep into the tech. If we have any kind of standardisation or compliance of that regard that they're doing something that is actually AI and working AI models and whatnot then I'm pretty sure it would be positive.

Martin Kambla
Timbeter

3.3. Impact of the AI Act on companies' reputation and customer perception

Overall, participants find that the AI Act may **improve reputation and overall customer perceptions**. For participants that support other businesses in being compliant, being ahead of the curve will ensure a competitive edge is maintained.

According to many participants, the AI Act will impact positively on the reputation of vendors and is expected to create the need for trustworthy AI solutions, even for low-risk AI applications. Businesses are expected to prefer service providers that can provide an assurance label indicating that their AI systems perform effectively and that any potential risks have been reduced or eliminated.

This will be likely true not only for companies classified as high risk, but also for those seen as minimal or limited risk, and as such it could lead to a sector-wide change.

The main angle of concern is driven by the **risks of non-compliance**. There is little understanding at this point of the full extent of not being compliant. Businesses need to ensure they do not cause themselves reputational damage due to this.



Acknowledgments

This report was completed by interviewing companies nominated to the Future Unicorn Award since 2018. The following representatives of 9 companies were interviewed:

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Omina Technologies, Martin Canter & Anita Prinzie, Belgium

Timbeter, Martin Kambla & Anna-Greta Tsahkna, Estonia

Veriff, Aleksander Tsuiman, Estonia

WithSecure, Antti Koskela, Finland



About Savanta

Savanta provides specialist research and insight into reputation management, public policy and communications. Our inform and inspire framework allows us to partner with clients with a flexible approach, arming you with the ability to quickly poll an audience of interest, or utilise our in-house expertise and capability to deliver impactful research helping to drive commercial opportunities and strategic change.

In July 2019, ComRes joined Savanta, which has vast experience of research and consulting with clients on their brands, communications and business strategies. Savanta is a member of the Market Research Society and ESOMAR, as well as being an associate member of the Management Consultancy Association (MCA). As such, it is committed to the highest standards of research practice.

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Savanta:

DIGITALEUROPE represents the voice of digitally transforming industries in Europe. We stand for a regulatory environment that enables businesses to grow and citizens to prosper from the use of digital technologies.

We wish Europe to develop, attract and sustain the world's best digital talents and technology companies.

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