AI Act Impact Survey

Exploring the impact of the AI Act on Startups in Europe

12 December 2022

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Foreword

Participating Initiatives

In each of our country's AI strategies as well as in the European one, we aim for global leadership in AI. AI is considered a most strategic and transformative technology with a major impact on our industry as well as society. This is also the reason why our institutions exist - be it established by the national governments or from the private sector. We all strive for achieving the goals of our AI strategies and share common targets:
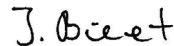
- Competitiveness: AI is already used as a strategic asset of nations. We need to foster digital sovereignty by staying relevant and competitive from SMEs to industry leaders.
- Trustworthiness: AI will affect us all. We want AI solutions based on European values in high quality.
- Speed: There is a global race. We should not be the ones walking.

Having received the feedback from our innovation ecosystems on the AI Act which is outlined in this document, we strongly advocate in all the discussions about potential risks and negative effects that we do not forget how AI can be used to help achieve our targets in the European Green Deal, Healthcare, Digital Sovereignty or other dimensions. The current strong imbalance in the discussions about the regulation will move us from being the shapers to becoming shaped by others. We would lose our innovative power in AI.

We hope that the voice of a truly European AI ecosystem will be useful in the discussion of AI regulation in Europe.

Andreas Liebl
appliedAI

Jörg Bienert
KI Bundesverband

Caroline Chopinaud
Hub.France.AI

Clemens Wasner
AI Austria

Jos van der Wijst
NL AI Coalitie

Piotr Mieczkowski
AI Poland

Mikael Ljungblom
AI Sweden

Startups centers

"The business plans of the next 10,000 startups are easy to forecast: take X and add AI"
— Kevin Kelly, Founding Executive Editor of Wired Magazine

This quote from 2015 visualizes the importance of artificial intelligence for startups and the innovation ecosystem of countries. Global investments in AI startups more than doubled from 90bn USD (2020) to 207bn USD (2021) [OECD.ai 2022]. While investments in AI startups in the US (53%) and China (23%) make up for the most of AI investments, the EU lags behind with 6%. Combining three of the largest startup centers in Europe, we see that close to 50% of the startups that we host per year in one way or another use AI which visualizes the relevance of AI for innovation also in Europe. It is essential that we consider AI as a means for innovation made in Europe and that we support startups in using this technology to be able to compete on the global market. We were alarmed by the feedback of startups and investors with regards to the effects of the current version of the AI Act. We urge policymakers to rapidly engage into a constructive dialogue with the players in order to find balanced solutions that would regulate AI while not harming the innovative potential of Europe.

Stefan Drüssler

Chief Operating Officer
UnternehmerTUM
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Executive summary

We talk about high-tech startups. The innovation engine of our economy that works on the latest technologies with AI experts as employees.

- We voluntarily limit Europe's innovative power by introducing the AI Act in its current state. If we decide on doing this, we need to think about substantial support in parallel.

- Other SMEs with less skilled employees will face even more challenges, because besides BigTech from abroad and a few local companies, it is the Startups that make AI accessible to the broader economy.

In summary

- The 113 EU-based AI Startups in this survey drive AI Innovation by developing diverse AI Systems, with both specific and generic purposes.
- Now being somewhat competitive, 73% of the surveyed VCs expect that the AI Act will reduce or significantly reduce the competitiveness of European Startups in AI.
- 33% - 50% of the AI Systems would classify as High-Risk which goes way beyond the assumption in the Policy Impact Assessment by the EU Commission (5-15%).
- 45% would consider their solution as a General Purpose AI.
- 50% of the AI Startups believe the AI Act will slow down AI Innovation in Europe. 16% consider stopping to develop AI or relocation outside the EU.

- For High-Risk AI Systems, the additional requirements and obligations are a significant challenge for startups in terms of technical and organizational complexity and compliance cost.
- All relevant indicators for VC investments for high-risk startups will decrease.
- VC investments shift toward AI Systems with a specific purpose, in low-risk applications, and, to some extent, to non-AI startups and outside of Europe.

While this data reflects only a small fraction of the European Industry, it is the one driving innovation. Feedback from established SMEs as well as larger European companies indicates similar challenges. Large startup nations around the world like the US, UK, China, Israel support AI startups to grow in the global race to leadership in AI. Yet, startups in the EU will start with the burden of additional cost, slowed down innovation and lower valuations and VC investments. Exceptions for SMEs do not help as those startups want to grow and they need to consider compliance from the beginning if they don't want to redo all the work once they grow beyond a certain threshold.

There exist several options to lower the impact on the startup and innovation ecosystem in Europe. Each of them can and should be addressed for Europe to stay competitive in the global race to AI leadership.

Image generated by Dall-E 2 with the prompt:
"Mood of a tech Startup ceo after being told that her company has to follow new regulations that are intended to protect health, safety and fundamental"

Section 1

Survey Participants

Image generated by Dall-E 2 with the prompt:
"AI Startups and VCs from different European countries offer views on the upcoming AI Regulation, Corporate memphis style in grey blue yellow and white colors"

AI Startups

65% of all startups familiarized themselves with the AI Act before the survey with Netherlands (89%) and Germany (80%) leading and Poland being the last knowledgeable.

Of the surveyed startups, 96% are providers of AI Systems that are meeting the Definition of AI System in the meaning of the AI Act[1].

The vast majority of the surveyed solutions meet the definition of AI System, bringing them into the scope of the AI Act. By implication, those startups developing the AI Systems would be in the role of the provider, thus facing additional obligations through the AI Act, in particular if their AI Systems classifies as high-risk.

> *"Regulation is needed, but it must not hamper the innovation of the European economy, especially for SMEs, which cannot afford lawyers and to investigate compliance with the growing number of unclear requirements. European SMEs need simple and clear regulations."*
>
> - Chloe Pledel
> Chef de projets européens,
> Hub.France.AI

> *"Higher awareness in Germany confirms the importance of mandatory association membership and the allocation of public funds for public education or organization activities. Poland needs to catch up."*
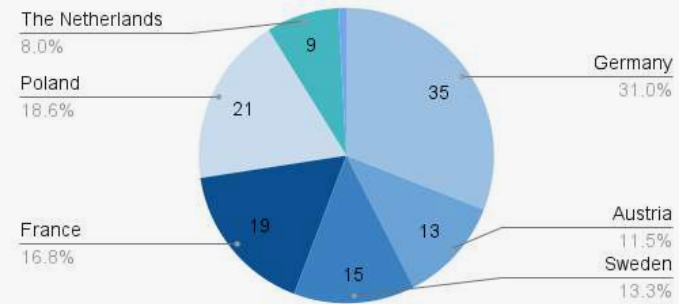>
> - Piotr Mieczkowski
> Managing Director, AI Poland

Target group: AI Startups and other AI developing companies
Countries of data collection: Austria, France, Germany, Poland, Sweden The Netherlands
Count of participating Startups: N=113
Period of data collection: mid-October to mid-November 2022
Questionnaire: See Appendix A

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1   Considering AI System(s) that:
   • Uses machine learning and/or logic- and knowledge based approaches
   • Operates with a certain level of autonomy
   • Produces outputs such as content (generative AI systems), predictions, recommendations or decisions

A board set of start-ups across Europe knowledgeable about AI participated in the survey

In which country is your company located?

The Netherlands 8.0% — 9
Poland 18.6% — 21
France 16.8% — 19
Germany 31.0% — 35
Austria 11.5% — 13
Sweden 13.3% — 15

European AI Innovation is well balanced between specific purpose AI, generic solutions and tools for AI development

What type of AI Application are you developing?

- Solution for a specific industry (e.g. a healthcare app) — 32%
- Technology service independent of function or industry (e.g. video analysis, CV tool, anomaly detection solution) — 31%
- Solution in a specific functional area (e.g. Marketing tool, Production optimization) — 26%
- Tool for AI development (e.g. MLOps, Model library, explainability tool) — 12%

Venture Capital Firms

Venture Capital fuels the innovation ecosystem. Their reaction on the AI Act will heavily affect the future health of the AI startup landscape which makes them an important voice about the impact of the AI Act.

AI Act Awareness

Only 60% familiarized themselves with the AI act before the survey (on a superficial level). 40% acknowledged that they need to familiarize themselves more with the risk categories.

Investment volume

The participating VCs represent a broad range from small VCs that plan to invest less than €10 Million up to €500 Million. The median participant plans to invest €10-50 Million. The participating VCs are only partially investing in AI startups (from 10%) up to specialized VCs where 100% of their portfolio companies use AI.

> *"The people discussing and writing AI Regulation are like a bubble inside the AI bubble, which, in itself, is relatively small compared to the rest of the European industry. Yet, the rules affect the Union market and the results show that more and wide communication is needed to avoid surprises."*
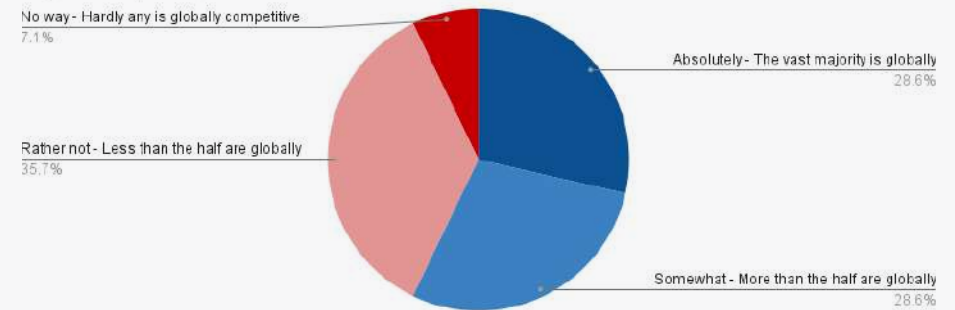>
> - Till Klein
> Team Lead Trustworthy AI, appliedAI Initiative

Target group: Venture Capital Firms
Countries of data collection: Europe
Count of participating Startups: N=15
Period of data collection: Early-November until Early-December 2022
Questionnaire: See Appendix B

Already now, VCs have a mixed impression of the global competitiveness of European AI Startups

Q Do you think EU-based AI Startups are globally competitive? (N=14)

- No way - Hardly any is globally competitive: 7.1%
- Rather not - Less than the half are globally: 35.7%
- Absolutely - The vast majority is globally: 28.6%
- Somewhat - More than the half are globally: 28.6%

The Funds represent all types of funds - from VCs specialized in AI to VCs that have only minor parts of their portfolio in AI startups

Q What share of the startups you hold equity in is using AI as part of their offering? (N=14)

- 90-100%: 7.1%
- 70-80%: 7.1%
- 60-70%: 7.1%
- 50-60%: 14.3%
- 40-50%: 14.3%
- 30-40%: 28.6%
- 20-30%: 7.1%
- 10-20%: 14.3%
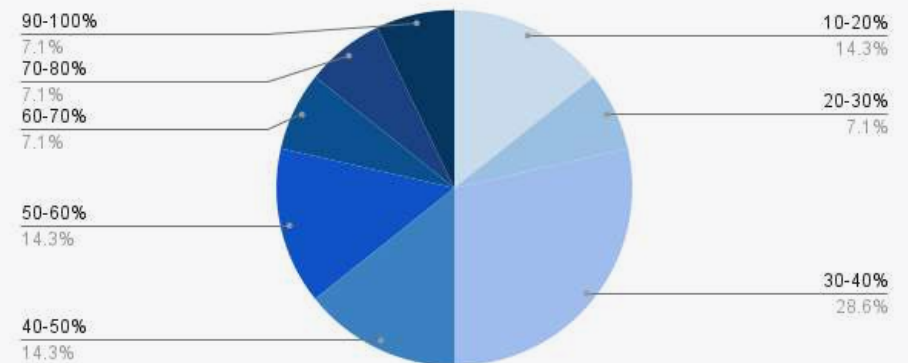
Section 2

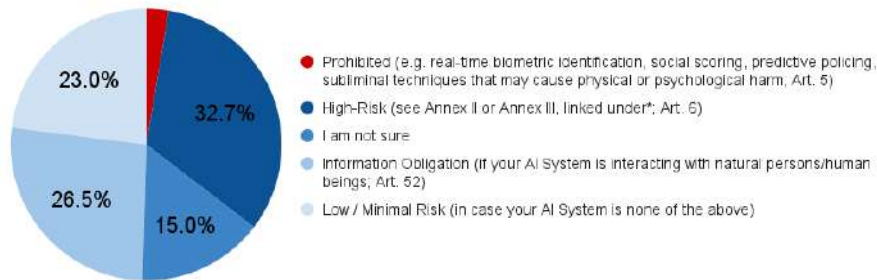# High Risk AI Systems

Image generated by Dall-E 2 with the prompt:
"The share of high-risk AI-Systems is higher than assumed, some startups consider relocation outside the EU, some VCs consider moving funding away from European AI , Corporate memphis style in grey blue yellow and white colors"

High Risk AI Systems

Nearly 33%-50% of the respondents would classify their AI System as a "high-risk" System according to Annex II or III, which is more than double than the 5-15% assumed in the Impact Assessment by the EU.

A central assumption of the EU Impact Assessment does not hold: 33% of the Startup Solutions could be classified as high risk

Q Considering the flag-ship Use Case of your Startup/company, in which risk class of the AI Act is it going to fall?* (N=113)

- 23.0%
- 32.7%
- 15.0%
- 26.5%

- Prohibited (e.g. real-time biometric identification, social scoring, predictive policing, subliminal techniques that may cause physical or psychological harm; Art. 5)
- High-Risk (see Annex II or Annex III, linked under*; Art. 6)
- I am not sure
- Information Obligation (if your AI System is interacting with natural persons/human beings; Art. 52)
- Low / Minimal Risk (in case your AI System is none of the above)

"We need a revision of the assumptions for high-risk solutions and clear and easy-to-read regulations."

- Chloe Pledel
Chef de projets européens, Hub.France.AI

"The feedback from the startups confirms other analyses done by appliedAI. Based on the 4th draft compromise text, the amount of high-risk AI cases is much higher than anticipated. We must reduce both uncertainty as well as total amount of high risk cases."

- Andreas Liebl
Managing Director, appliedAI

General Purpose AI

General Purpose AI Obligations are written with Large Models from BigTech in mind, but many European Startups are in the scope, too.

45% of the surveyed Startups consider their AI System to be GPAI, making them subject to the obligations of GPAI providers. The impact of this development has not been assessed, as General Purpose AI was neither considered by the 2021-Draft by the EU Commission nor by the accompanying Policy Impact Assessment.

Startups that are part of AI Value Chains not only need to meet the general AI Act obligations, but also need to set up contractual arrangements to exchange relevant information with their customers, creating additional burden and complexity.

45% of the AI Systems by Startups could be classified as General Purpose AI

Q Do you consider your AI System to be of' 'general purpose'? (N=112)

- I'm not sure 13.4% — 15
- Yes 44.6% — 50
- No 42.0% — 47
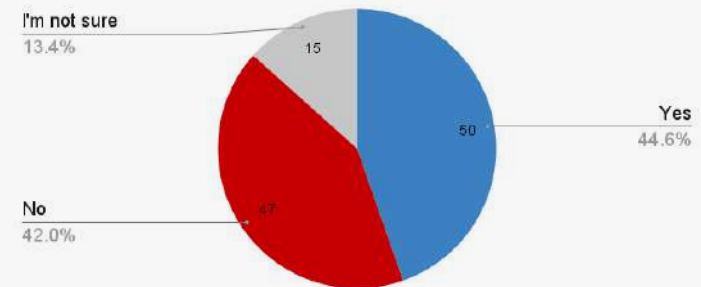
"Regulating GP AIs is a reasonable idea as the most large models are provisioned from outside the EU. Yet, the proposed approach creates many challenges and implications that might be severe, because GP AI regulation was not considered in the Policy Impact Assessment and in the design of the AI Act."

-Till Klein
Team Lead Trustworthy AI, appliedAI Initiative:

Impact on Innovation & Competitiveness: Startups

51% of the respondents expect a slow down of their AI development activities as a result of the AI Act.
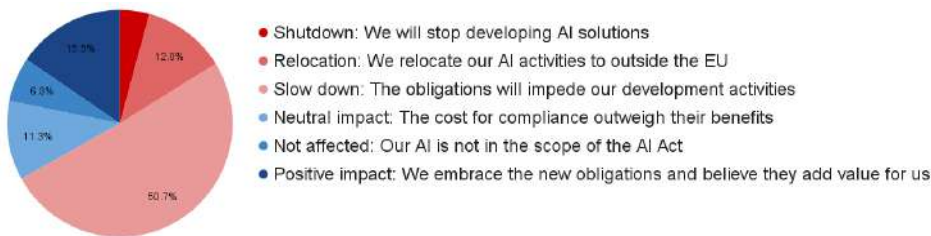
Around **12%** of the startups say they consider relocating outside the EU or stop working on AI altogether.

Another **~16%** expect a positive impact of the AI Act on their business.

The main beneficiaries of the AI Act in the global Race to AI are expected to be outside of Europe, specifically US-based BigTech companies and AI startups outside the EU.

Two thirds expect a negative impact of the AI Act on AI Innovation in Europe

Q   What impact do you foresee for your company and how are you going to respond to those obligations? (multiple choice question, N=142)

- ● Shutdown: We will stop developing AI solutions
- ● Relocation: We relocate our AI activities to outside the EU
- ● Slow down: The obligations will impede our development activities
- ● Neutral impact: The cost for compliance outweigh their benefits
- ● Not affected: Our AI is not in the scope of the AI Act
- ● Positive impact: We embrace the new obligations and believe they add value for us

"As the EU is already behind in terms of innovation in AI, this slowdown could crush the AI ecosystem in the EU as the impacted companies also consider leaving the EU for a territory with a more favorable regulation."

\- Chloe Pledel
Chef de projets européens, Hub.France.AI

"In addition to all the crises shaking the continent, a large part of the innovation industry is being torpedoed right now. Investments in AI are now becoming several hundred thousand euros more expensive without gaining any added value. This is a self-made competitive disadvantage that other geopolitical regions do not have."
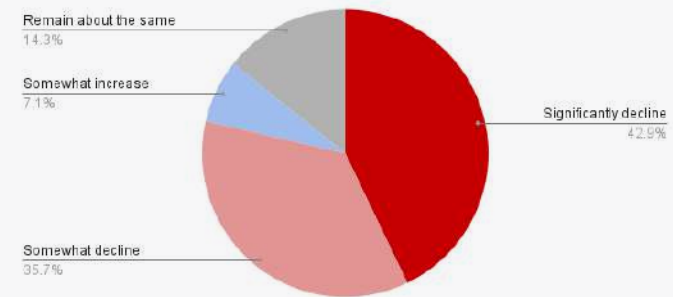
\- AI startup

Impact on Innovation & Competitiveness: VCs

Almost three quarters of the participating VCs expect that the AI Act will decrease the global competitiveness of AI Startups made in Europe.

VCs see a drastic worsening of Europe's competitiveness in AI and will focus on more incremental innovation

Q   How is the AI Act likely to change the global competitiveness of EU-based AI startups? (N=14)

Remain about the same
14.3%

Somewhat increase
7.1%

Significantly decline
42.9%

Somewhat decline
35.7%

Section 3

Consequences of working on high risk AI Systems

High-Risk Requirements

The perceived level of difficulty declines along the AI/ML lifecycle. Data Governance and Risk Management are considered the most difficult. Quality Measures such as Accuracy, Robustness and Cybersecurity are also rather difficult, but not as much. Record keeping, human oversight and technical documentation appear doable.

For most requirements, less than 25% of the respondents rate a requirement as easy, hinting at the increased complexity for providers of high-risk AI Systems.

....

Complexity is rising: Data Governance and Risk Management are seen as the most difficult high-risk requirements

Q How easy/difficult are the Requirements for High-Risk AI Systems?

"Startups need to develop their solutions already now in compliance with the requirements of the AI Act but there are no standards or tools existing. We immediately need an ecosystem that develops those tools in parallel to standards and AI Act implementation."

- Andreas Liebl,
Managing Director of appliedAI

Obligations for providers of High-Risk AI Systems

Startups struggle with demonstrating compliance at the initial placing on the market and with maintaining compliance during the deployment phase.

Many Startups might develop only one or a few AI Systems, which are not yet deployed at scale, .i.e. making an conformity conformity assessment difficult in the absence of established procedures for the entire lifecycle, which leads to additional complexity on the organizational level. In contrast, large companies tend to offer existing products for which a conformity assessment is necessary, meaning they have established structures and processes for that very purpose.

Meeting the obligations of high-risk providers might be relatively easier for large companies with existing Quality Management Systems and established processes along the product lifecycle that meet other Union Regulation, creating an unfair advantage compared to startups and SMEs.

....

Q How easy/difficult are the Obligations for providers of High-Risk AI Systems?
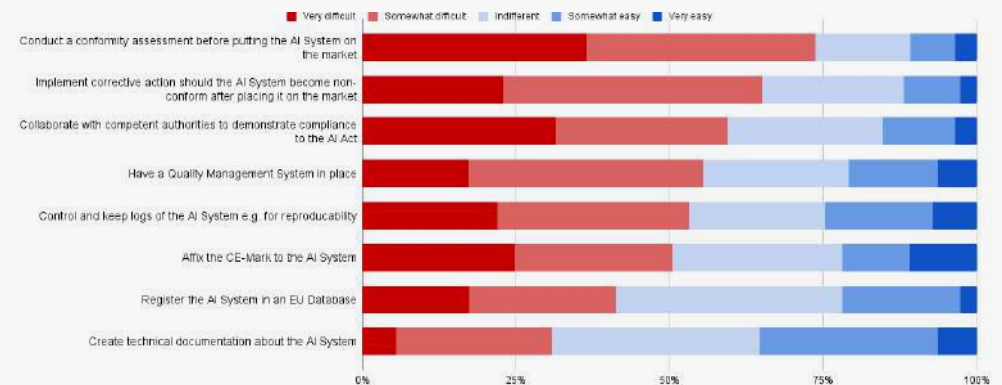
"The requirements for developing high-risk AI applications threaten to paralyze our SMEs at the expense of global organizations that can afford the extra burden. Jobs will move outside Europe as a consequence."

- Björn Hovstadius
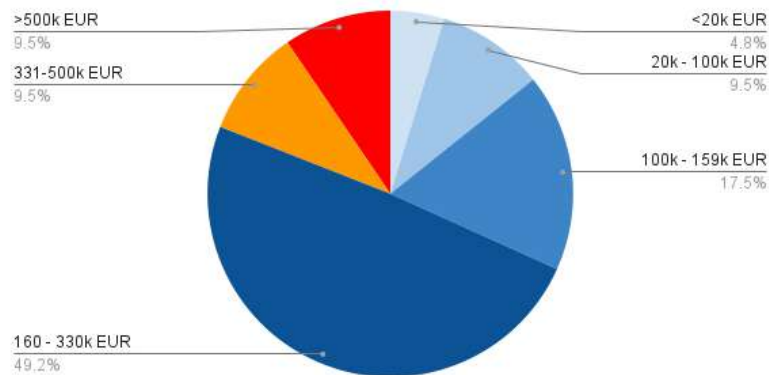Manager International partnerships, AI Sweden

Compliance cost

50% are within the estimated cost range between 160k - 330k EUR.

Nearly **~20%** of the respondents expect somewhat or significantly higher cost for compliance.

Half the startups estimate additional cost for compliance within the assumption in the Policy Impact Report, but they do not know how to afford them

Q What cost of compliance do you estimate for your company? (Free text; N=63)

>500k EUR
9.5%

331-500k EUR
9.5%

<20k EUR
4.8%

20k - 100k EUR
9.5%

100k - 159k EUR
17.5%

160 - 330k EUR
49.2%

"As a project-based service provider, we estimate the costs for our company to be very high to existentially threatening, as the multitude of "AI products" our company develops will lead to multiplied QMS and conformity assessment efforts. . We do not expect to be able to effectively pass these costs on to our customers."
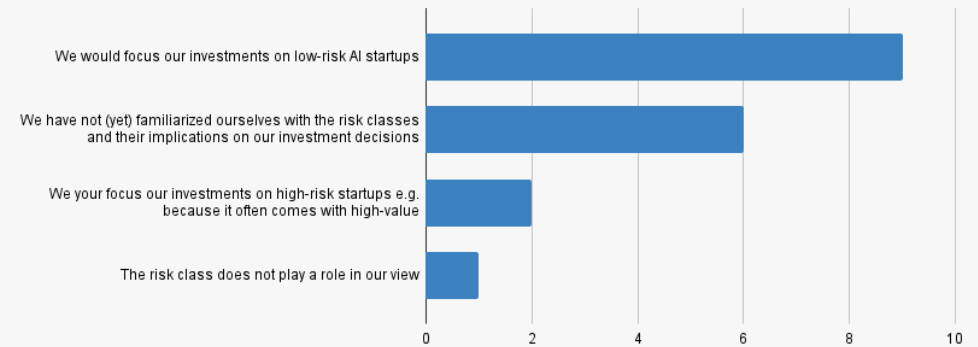
- AI Startup from Germany

"Not estimable. We are 4 and do not have a quality referent."

- AI startup from France

Financial impact - attractive types of innovation

The AI Act is considered to lead to less disruptive innovation and a shift towards smaller incremental ones.

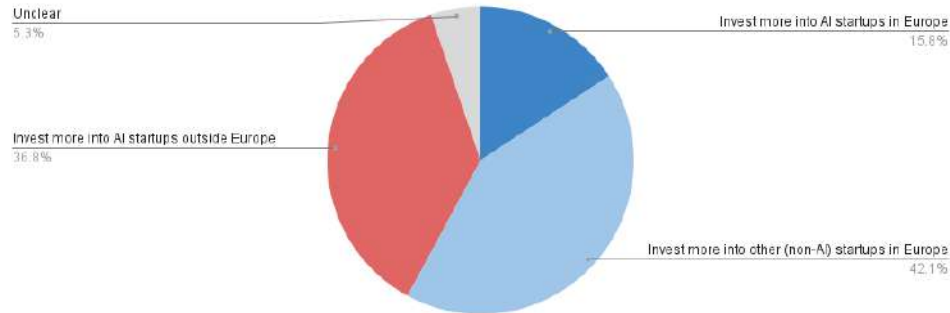**Q** How do you consider the risk category in your investment decision? (Multiple-choice question; N=18)

"I expect, that overall investments will be reduced the higher the regulation is for the sector. High-risk solutions might get no funding at all. I also see currently no trend for VCs to invest into General AI or Large models unless government funding will be part of it."

- VC from Germany

Re-allocation of VC Funds: Regional Focus

The available VC-Funding for AI Startups is likely to shrink under the AI Act and partially move toward Startups outside the EU and non-AI technologies

Q With the AI Act being on the horizon, do you consider moving investments? (Multiple-choice question; N=19)

Unclear
5.3%

Invest more into AI startups in Europe
15.8%

Invest more into AI startups outside Europe
36.8%

Invest more into other (non-AI) startups in Europe
42.1%

"This is short of a catastrophe. AI solutions are key to addressing many of our societal challenges in Europe. International talent will go to other markets. If we scare away investments and jobs from our member states we will not be able to develop the solutions needed".

- Björn Hovstadius
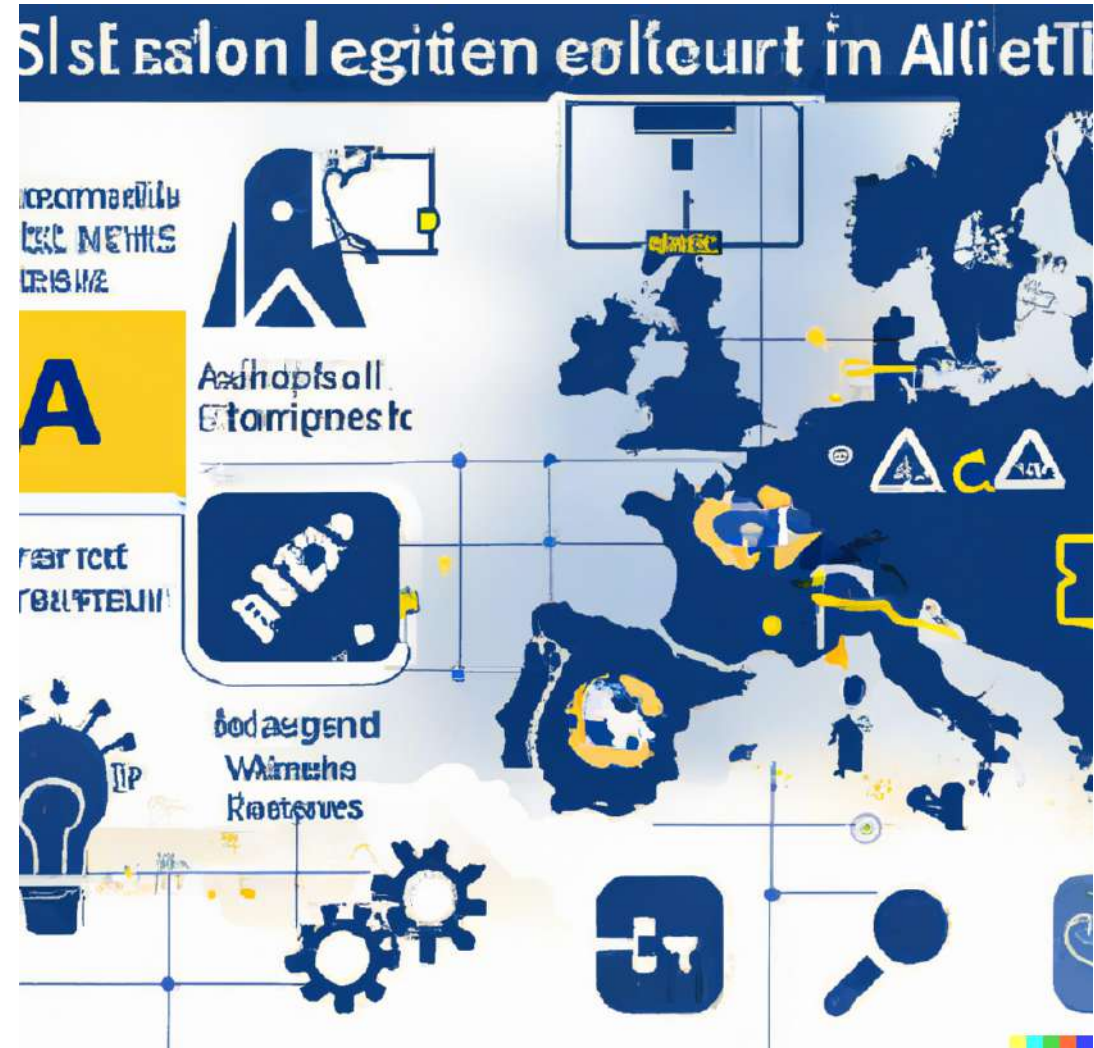Manager International partnerships, AI Sweden

Image generated by Dall-E 2 with the prompt:
"AI Systems that can adresss societal challenges in Europe are not implemented because of a lack of funding and talent, flat illustration in grey blue"

Re-allocation of VC Funds:
high-risk vs low risk AI Systems

Low-Risk AI Startups might see a minor decline of VC interest and anticipate additional efforts to win deals. A solid rationale for the low risk classification needs to be in place, specifically if the Use Case falls into the category of General Purpose AI.

"It is clear that even low risk AI startups are affected by the proposed legislation. Just the risk of a startup being classified as high-risk or General Purpose creates uncertainty. VCs hate uncertainty. They will instead invest in markets outside of Europe with clear rules. Europe will lose investments and jobs creation."

- Björn Hovstadius
Manager International partnerships, AI Sweden

Startups developing high risk AI Systems are less attractive to investors

Q If a startup falls into the "high-risk" Class in the AI Act, how does this affect the valuation and attractiveness of the startup? (N=15)
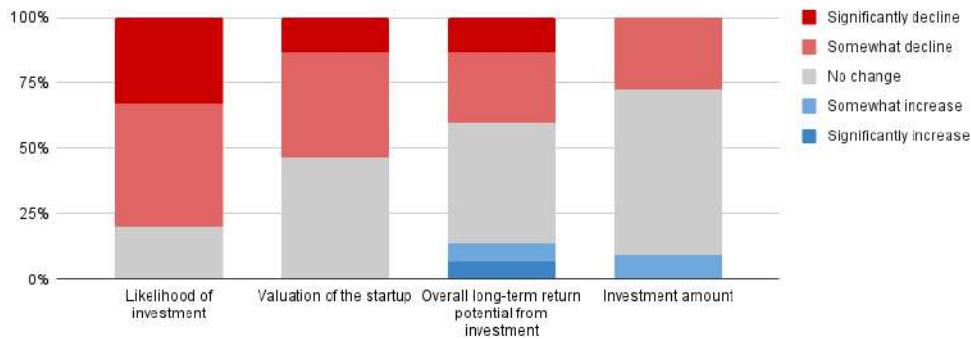
Same question, inverted scale
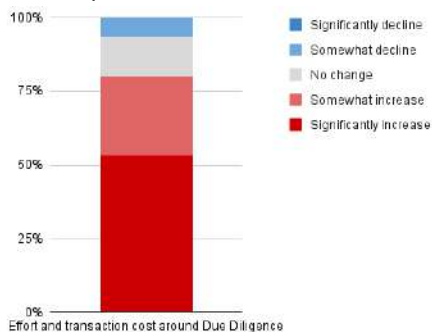
AI Startups with low-risk AI Systems have slightly improved access to VC investments

Q If a startup falls into the "low-risk" Class in the AI Act, how does this affect the valuation and attractiveness of the startup? (N=15)

Same question, inverted scale

Startup Story: A Healthcare Startup about the Impact of the AI Act

Q Please describe your use case. What are the central benefits for the user and the broader society?

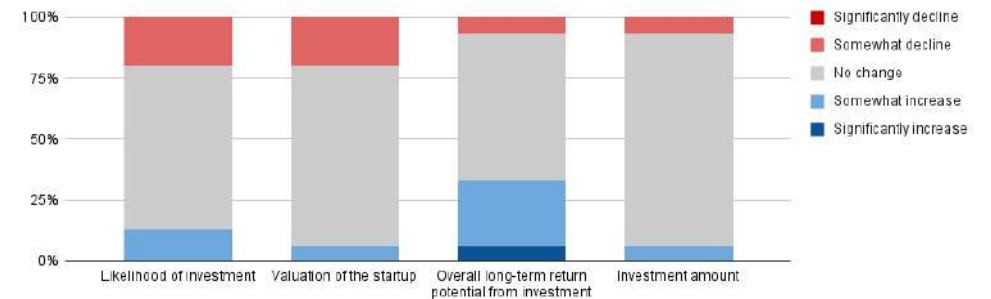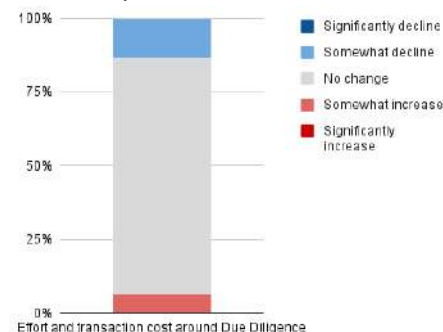**A** We are active for around 2 years and develop AI in the Creative sector (e.g. Music) and in Healthcare. The former is fun, but the latter saves lives, which is where we see the biggest impact.

Case 1
Statistics in Medical Research (in deployment)

So far, we used statistical methods to support medical research. For instance, in medical studies about medical treatments such as post-OP recovery, where we help surgeons and researchers to determine the discriminating factors for patients at risk. Traditional methods often point to characteristics like gender, age and weight, but we can be more specific and capture the relationships amongst variables, e.g. how a pregnant woman might react to a treatment x weeks after the surgery.

> Note from the interviewer: This System would be considered AI under the broad definition, but might be exempt from the AI Act (?), because it is in the field of research.

Case 2: Brain pressure prediction (under development)

Patients in intensive care units may experience increased brain pressure, which, when it occurs, needs to be reduced to prevent long term damage. If the pressure is above a certain threshold, only invasive measures can reduce it, which are risky and come with side-effects. To prevent such measures,

early and weak signals can be detected using our AI/ML system that is trained on the basis of biometric data from the intensive care unit, such as heart rate, blood pressure, and other inputs. The system alerts the medical team if a high-pressure event is expected or detected, to enable swift and minimal-invasive intervention.

Case 3: Prediction of blood bags demand (canceled due to GDPR)

In Germany, there is a shortage of blood reserves across hospitals, yet we observed that many blood bags are being wasted because of short expiration dates and imprecise planning of when, which type of blood is needed. One blood bag may cost several hundreds Euros (e.g. platelet concentrates) and some hospitals plan their blood purchases with a moving average of some four weeks, when, in fact, many more factors matter, e.g. planned operations or whether certain physicians are working.

We trained an AI/ML model which showed promising results for predicting the demand of blood bags on a certain day, which could minimize the waste of blood donations at scale, but the project was stopped, because the data protection officers at the involved hospitals had no means to give access to necessary training data.

> *"The existing regulation (MDR, GDPR) are already a struggle, but we cannot stumble an entire Marathon with the AI Act on top"*

Impact

Q How is the upcoming EU AI Act going to affect the way your company develops AI?

A The Brain pressure application would be a Class IIa Medical Device and require a conformity assessment under the Medical Device Regulation.

That in itself is a huge burden, because the certification by a notified body costs us some €300-400k plus we would have to wait around 12 months before our application can be assessed, because notified bodies are a bottleneck to the market. Unless we pay a "priority fee" to reduce the waiting time, which is beyond our budget.

The AI Act increases the uncertainty, both, for us and the hospitals. They do not know the implications and their legal departments are conservative, meaning they rather do nothing before they do something wrong. On our side, we cannot estimate the additional effort, expertise, and cost for compliance.

I've done my Masters' degree in Explainable AI and most models cannot be fully explained, hence I am not sure what policy makers are expecting. Many of my fellow graduates are moving to the USA to work for BigTech. Working in a startup I make half of their salary, which is ok, because with our medical applications we are making a difference. But looking at the AI Act, we seriously consider stopping our AI developments in high-risk areas and focus on the Creative Arts, which is also fun, but it won't save lives.

Startup Story: A Healthcare Startup about the Impact of the AI Act

Recommendation

Q What measures / changes from the EU or national government would help to minimize the burden and to improve innovation?

A Policy makers should not only focus on preventing things that are dangerous, but also enable things that create value. It is fair to regulate AI, but we should not forget about the opportunities that technology offers to us.

As a startup, we are always collaborating with other organizations (hospitals in our case) who are asking us about AI, how it works, and how we ensure compliance. This is fine, but the AI Act will raise new questions, and if we spend all time explaining the regulations to our partners, we have limited time to develop great technologies, which is our strength. Hence, we wish for targeted information campaigns that explain to all relevant stakeholders (e.g. hospitals) what the AI Act is about and what can and cannot be done.
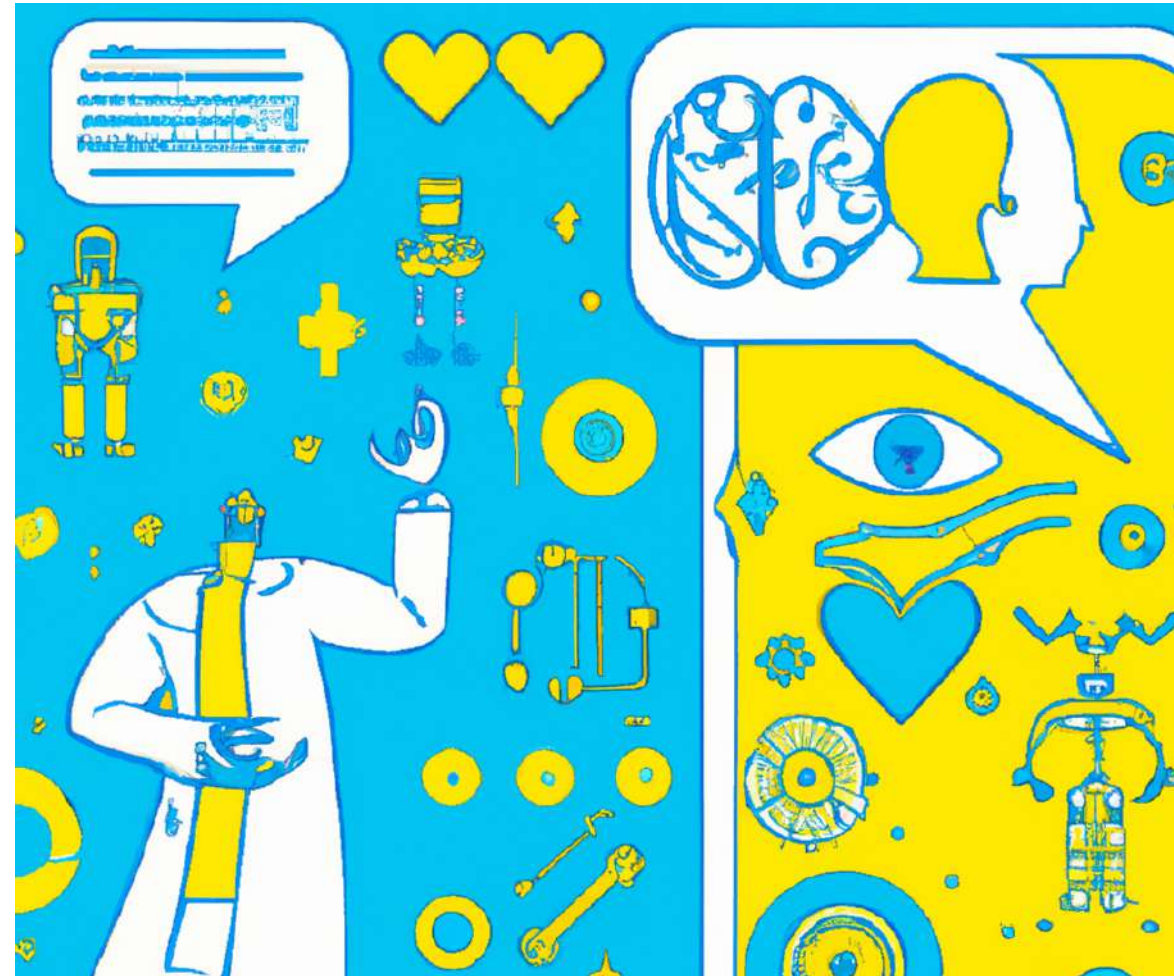
Image generated by Dall-E 2 with the prompt:
"A startup CEO in Healthtech wishing for an information campaign about the upcomming AI Regulation, because they cannot explain all the requirements to their partners such as hospitals, Corporate memphis style in grey blue yellow and white colors"

Section 4

Accelerating Compliance

Image generated by Dall-E 2 with the prompt:
"Policy makers, startups, corporates and certification bodies engaging in trial and error of new AI regulations in a regulatory sandbox, flat illustration in grey blue yellow and white colors"

Support for AI Startups

Most Startups are looking for expert knowledge through practical guidance, case studies or consultation.

76 Startups have a need for additional funding to cope with the growing compliance cost.

Best practices and additional funding are key drivers for compliance

Q What kind of support or assistance would you like to see for meeting the requirements and obligations from the AI Act? (Multiple choice question; N=239)

Support Needed	Count
Best practice methods and templates e.g. guidance documents	82
Additional funding to cope with the additional efforts	76
Case studies of how other companies apply the AI Act	62
Consultation or coaching	58
Technical tools to achieve compliance e.g. on data-related topics	57
Training & education offers	53
Reliable (binding) Q&A or references for specific questions	48
Exchange with other companies, similar to yours	43
Direct communication with policy-makers	38

"European Startups and SMEs need help to implement the AI Act. Without a series of measures, innovation in Europe will be delayed."

- Chloe Pledel
Chef de projets européens, Hub.France.AI

"Startups have a clear opinion about what they want as support. Most of the aspects are not or only in parts addressed in the AI Act or the Coordinated Plan."

- Andreas Liebl
Managing Director of appliedAI

"The risk of AI-Startups being overwhelmed by the AI Act is a real possibility, as such the Act must be applicable and handleable for Startups."

- Jörg Bienert
President German AI Association

Regulatory Sandboxes

AI Startups have clear expectations toward Regulatory Sandboxes

Q The AI Act foresees the setup of so-called 'Regulatory Sandboxes' which are intended for 'trial and error', i.e. for implementing the AI Act "without being charged" when things go wrong.

What are your expectations for such a Sandbox in your country? What kind of services, actors or waivers would you like to see there? Please elaborate

A Answers (direct words from respondents):

Access & Utility:

- **Leadership**: Extremely clear and transparent structures, neutral leadership (not through politics or company representatives or connected

- **Access:**
  - A simple interface so you don't have to spend excessive development time to use the sandbox.
  - It should be available as soon as possible. Fast and secure regulatory implementation.

- **Funding:** Additional funding to meet extra efforts.

- **Commercialisation:**
  - I can't imagine how this is going to work. The AI solution needs paying customers. They exist in the real world and not in sandboxes.
  - (Potential) customers are very insecure and don't dare to do anything with AI for the time being, because they could be prosecuted for it very soon.

- **Flexibility:** Accessibility, adaptation to individual needs

Legal Aspects:

- **Co-creation:** Make recommendations on what needs to be improved and do not directly impose regulatory fines or penalties on the founders.

- **Interventions:** The question is whether the ANSSI (French authority for the security and defence of information systems) intervenes in the regulation of the sandbox and can create alerts of flaws. The INRS is also concerned for Health and Safety at work.

- **Intellectual Property:** It's very complicated without risking disclosure of how a company solved technical problems or provided data sets for testing, especially when intellectual property rights are involved.

Testing & Quality

- **Scope:** it should be possible to carry out any type of experimentation, including on borderline cases (military, biotech, cyber, etc.), even if it means having a specific level of monitoring.

- **Test Users:** It would be ideal if there were some volunteer users you could book to see the results as an objective third reference.

- **Audits:** Regulatory sandboxes should aim at conducting holistic audits of prioritzed use cases with high-risk AI systems that include all relevant stakeholders such as use case owners, auditors, auditing tool providers and regulatory authorities. Legal advice. Unclear to date.

- **Continuous Compliance:** Stay up to date with the laws automatically, Provide actionable points on warnings and errors while running the system

through such sandboxes, help reduce the time for compliance in all ways possible. Probably easy fixes can be offered through static code analysis and so on. Acts against data monopoly.

- **Quality Data**
  - Common test datasets (learning, evaluation and bias detection). Evaluation grid.
  - Protected area with synthetic data for comprehensive testing (quality assurance)
  - Doubtful about the feasibility for the insurance field, despite a very high interest in the subject, which would benefit from being treated on a national scale. Detailed anonymised statistical data from the French could certainly help improve insurance products and their recommendation.

Expertise Building

- **Education:** Training and education opportunities

- **Best practice:** Have concrete examples or even a demonstration.

- **Compliance know-how:** (...) knowledge about other regulatory processes like that of medical device certification.

- **Sectoral Experts:** Strong availability of sectoral experts (CV, ...) for compliance in case of failure via a tool such as: Chat ". A/B testing, always useful.

- **Individual consulting:** Feedback on our solution with specific advice on how to mitigate/fix parts that would not comply with the regulation. If it is done by politicians... then there are a lot of problems

Recommendations by VCs to AI Startups

AI Startups should address the AI Act proactively, be aware of the own risk-class, and explore new opportunities

Q What is your recommendation to EU-based AI Startups?

A **Answers (direct statements) :**

"Prepare a dedicated Q&A on how the AI Act will impact your business before fundraising"

"Avoid the high-risk sector / consider compliance from the beginning /invent more solutions to monitor AI, manage it and help enterprises to be compliant."

"new regulations might open so far unknown opportunities; address them"

"Keep building - with enough utility for the user, technology will win over the long run"

"Risk mitigation: Be prepared for an AI Act audit of a VC, i.e. assess the risk as best you can (and ask for help from large VC/startup organizations) and identify ways to address or work around AI Act restrictions."

"Don't worry. Focus on buidling."

"Fight against early regulation."

"Keep a close eye on regulatory requirements and how that will impact the cost of development in the early stages."

"Create a parent company in the US that holds all the IP or risk getting impact by your own countries."

"Avoid having to deal with this regulation if at all possible."

Recommendations by VCs to Policy Makers

Policy makers should critically reflect on the need to regulate early stage AI startups and implement measures to accelerate their compliance

Q What is your recommendation to the policy-makers writing and voting on the AI Act?

A **Answers (direct statements) :**

"Let's educate ourselves - AI education for everyone first before making regulatory pushes"

"Try to help European StartUps. They will suffer more from this than Google & Meta (who can easily afford the best lawyers and certification consultants)"

"Don't regulate too early! Technology and use cases are still too volatile and AI technologies tend to be just a part of the products. Early regulation will hurt disproportionately and create an additional competitive hurdle for European companies."

"There is a reason for China and the US to wait to regulate it, don't want to kill innovation to soon to be the most competitive. No significant AI has come from EU and none will come if we are the first to regulate it.

"Our first investment in a significant high risk AI startup from EU we decided to do flip it to the US just for the risk of this kind of regulations."

"It is an important goal that only AI that safeguards the security and fundamental rights of EU citizens is developed and used in the EU, and it is good that a regulatory environment is being created for this. However, this framework must be balanced and must not restrict the innovative strength of Germany/EU as a business location. In my opinion, VCs will have to carry out much more precise checks and the burden will be immense, especially for very young innovative start-ups, so that in my opinion less private capital will flow into young companies. Politicians need to develop a more precise understanding of what early-stage start-ups can do and what restrictions are really necessary to achieve the above-mentioned goal. If you look at the results of the survey of start-ups on the AI Act, this has obviously not been achieved."

Policy Recommendations

Measures to protect, nourish and accelerate European AI Startups

1 Keep European Competitiveness in the center of the discussions

2 Reduce amount of high-risk cases: Narrow the High-Risk Criteria to get closer to the anticipated 5%-15% of affected AI-Systems

3 GP AI: Consider the role of Startups as GP AIs provider in the light of GP AI Obligations

4 Foresee bottlenecks and systematically debottleneck them e.g. in the area of 3rd party conformity assessments to not additionally slow down innovation

5 Conceptualise Regulatory Sandboxes as drivers for innovation in a protected, but attractive environment.

6 Update the Coordinated Plan and take the needs of European AI Startups into account, specifically in areas that are considered very difficult or costly. Reduce cost of compliance.

Image generated by Dall-E 2 with the prompt:
"Policy makers, startups, corporates and certification bodies engaging in trial and error of new AI regulations in a regulatory sandbox, photo realistic"

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Limitations

Our study represents only a share of the AI Startup community in Europe. There are no official numbers on the total population of AI Startups in Europe, but proxies are ranging from ~500 AI Startups in 2020 in France, Germany and Sweden[1] to 1600 AI Startups across Europe (incl. UK) in 2019[2].

Our study does not control for the level of proficiency about the AI Act. We did provide guidance material in the questionnaire, e.g. about the criteria for risk classification, but it is unknown to what extent the respondents are really familiar with the AI Act.

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1 source: www.ai-startups-europe.eu

2 source: https://medium.com/mmc-writes/the-disruptors-unique-insight-into-europe-s-1-600-ai-startups-part-1-d30f7b1967a1

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appliedAI is Europe's largest initiative for the application of leading edge trustworthy AI technology with the vision to shape Europe's innovative power in AI. appliedAI was formed as trustworthy initiative that acts both as enabler and innovator. Based on our ecosystem we strengthen the value creation building global AI champions.

Entrepreneurship Centres

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DTU Skylab is DTU's (Technical University of Denmark) living lab for innovation and entrepreneurship. We match state of the art technology and science with an ambitious and open community, where students, researchers and corporate partners meet to exchange knowledge and develop visionary solutions for real world challenges.

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Agoranov is an incubator for innovative startups. It has already incubated more than 450 startups, including 5 "unicorns" (valued at over one billion dollars), as well as many successful companies, such as Ÿnsect or DNA Script. Incubated startups have already managed to create more than 12,500 jobs and have raised over 2.5 billion euros from private funds.

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At UnternehmerTUM, visions turn into value. Our teams empower innovation enthusiasts to take entrepreneurial action. Together with start-ups and established companies, we drive tech ventures forward - from first idea to market leadership. In collaboration with the Technical University of Munich (TUM) and entrepreneur Susanne Klatten, we've been promoting future-forward start-ups such as Celonis, Konux, Lilium, inveox, and Isar Aerospace since 2002.

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The Netherlands AI Coalition is a public-private partnership in which the government, the business sector, educational and research institutions, as well as civil society organisations collaborate to accelerate and connect AI developments and initiatives. The ambition is to position the Netherlands at the forefront of knowledge and application of AI for prosperity and well-being. We are continually doing so with due observance of both the Dutch and European standards and values. The NL AIC functions as the catalyst for AI applications in our country.

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AI Austria is an independent think-tank and sees itself as a platform for the exchange of ideas on Artificial Intelligence. Through targeted networking, coordination and promotion of players from science, business, education and society, we want to contribute to the targeted and sustainable application of AI in Austria.

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AI Sweden is the Swedish National Center for Applied Artificial Intelligence, supported by the Swedish government and a wide range of partners representing academia, the private and public sector. AI Sweden's mission is to Accelerate the use of AI for the benefit of our society, our competitiveness, and for everyone living in Sweden.

Appendix A: Questionnaire for Startups

Are you....*

- Developing a solution for a specific industry (e.g. a healthcare app)
- Developing a solution in a specific functional area (e.g. Marketing tool, Production optimization)
- Developing a technology service independent of function or industry (e.g. video analysis, CV tool, anomaly detection solution)
- Providing a tool for AI development (e.g. MLOps, Model library, explainability tool)

> In a nutshell, the AI Act will regulate the development, marketing and usage of AI in Europe following a risk-based approach, meaning, the higher the risk of a AI System (low-risk, high-risk, prohibited) the stricter the regulatory requirements. High-risk AI covers safety-related applications across industries such as cars, airplanes, medical devices, or toys, but also certain areas of usage, including education, employment, law enforcement or critical infrastructure. High-risk AI needs to undergo a conformity assessment to meet requirements, e.g. on data governance, explainability, accuracy, cybersecurity and human oversight. Developers of high-risk AI face comprehensive obligations, too.

Have you heard about the AI Act before?

- Yes
- No

Is your company working on the development of AI System(s)?

An AI Systems that

- uses machine learning and/or logic- and knowledge based approaches
- operates with a certain level of autonomy
- produces outputs such as content (generative AI systems), predictions, recommendations or decisions

- Yes
- No
- I am not sure

Considering the flag-ship Use Case of your Startup/company, in which risk class of the AI Act is it going to fall?

See Annex II and Annex III of the AI Act as reference to determine if your AI is considered high-risk.

- Prohibited (e.g. real-time biometric identification, social scoring, predictive policing, subliminal techniques that may cause physical or psychological harm; Art. 5)
- High-Risk (see Annex II or Annex III, linked above; Art. 6)
- Information Obligation (if your AI System is interacting with natural persons/human beings; Art. 52)
- Low / Minimal Risk (in case your AI System is none of the above)
- I am not sure

If you are not sure, what information is missing on your side? What is unclear or ambigious? Please describe.

_____

_____

High-risk AI Systems have to comply with several requirements as a precondition for usage.

Please rate how difficult / easy you consider the implementation of these requirements.

Scale: Very difficult - Somewhat difficult - Indifferent - Somewhat easy - Very easy

- Risk management (Risk Mgt. along the ML Lifecycle, mitigate risk until acceptable)
- Data and data governance (Use high-quality training, validation and testing data, bias monitoring)
- Technical documentation (document the AI system before placing on the market)
- Record-keeping (logs-tracking, post-market-monitoring, person involved in the verification)
- Transparency and provision of information to users (User shall understand the system, provide instructions for use, metrics, limitations for usage)
- Human oversight (feature a human-machine interface, avoid automation bias, "stop button"
- Accuracy, robustness and cybersecurity (quality assurance, accuracy to be in instructions for usage, resilience against unauthorised access)

If your organization is developing AI, you are likely to fall into the role of a so called 'provider' in the AI Act. Providers of high-risk AI Systems face comprehensive obligations. Please review the obligations below and indicate how difficult / easy you rate their implementation:

Scale: Very difficult - Somewhat difficult - Indifferent - Somewhat easy - Very easy

- Have a Quality Management System in place
- Create technical documentation about the AI System
- Control and keep logs of the AI System e.g. for reproducability
- Conduct a conformity assessment before putting the AI System on the market
- Register the AI System in an EU Database
- Implement corrective action should the AI System become non-conform after placing it on the market
- Affix the CE-Mark to the AI System
- Collaborate with competent authorities to demonstrate compliance to the AI Act

The AI Act is going to pose obligations on the providers/developers of AI Systems, e.g. regarding risk management, data governance, robustness and transparency in the case of High-Risk AI Systems (see chapter 2 for details). What impact do you foresee for your company and how are your going to respond to those obligations?

- Positive impact: We embrace the new obligations and believe they add value for us
- Neutral impact: The cost for compliance outweigh their benefits
- Not affected: Our AI is not in the scope of the AI Act
- Slow down: The obligations will impede our development activities
- Shutdown: We will stop developing AI solutions
- Relocation: We relocate our AI activities to outside the EU

The EU conducted an Impact assessment of the AI Act and estimated the cost for compliance for an enterprise of 50 employees for one high-risk AI Product (covering the requirements for the AI System and the obligations for the company, e.g. introducing a Quality Management System (QMS)); see this report, Section 5.

- If the company has no QMS, "the set-up of a QMS and the conformity assessment process for one AI product is estimated to cost between EUR 193,000 and EUR 330,050."

- If the company has an existing QMS, it would roughly "pay EUR 159,000-EUR 202,000 for upgrading and maintaining the QMS, and bringing one AI product to market."

If you consider all efforts to comply with the requirements mentioned above, what cost of compliance do you estimate for your company?

_____

_____

Do you assume the AI Act will help you in the global competition (e.g. through more trust in your solution) or will help the competition outside the EU (Solution providers outside Europe have to comply too, when offered in Europe)?

- Helps the startups / AI developers in Europe
- Helps startups / AI developers in countries outside of Europe
- Helps the large cloud providers like Google or Amazon offering the developmet infrastructure
- Other:_____

Do you consider your AI System to be of 'general purpose' according to this definition:

"General purpose AI system' means an AI system that is able to perform generally applicable functions such as image or speech recognition, audio or video generation, pattern detection, question answering, translation or others; general purpose AI system may be used in different contexts and may be integrated in a range of other AI systems."

Background: Providers of General Purpose AI would have to foresee, if the user (e.g. a customer) uses the AI System for a purpose that might be considered high-risk, and if so, provide the necessary information to the user to be compliant with the AI Act (e.g. conduct a conformity assessment).

- Yes
- No
- I am not sure

What kind of support or assistance would you like to see for meeting the requirements and obligations from the AI Act?*

- Training & education offers

- Consultation or coaching

- Technical tools to achieve compliance e.g. on data-related topics

- Best practice methods and templates e.g. guidance documents

- Case studies of how other companies apply the AI Act

- Reliable (binding) Q&A or references for specific questions

- Exchange with other companies, similar to yours

- Direct communication with policy-makers

- Additional funding to cope with the additional efforts

- other (please elaborate below)

If you selected "other", please describe what kind of support on implementing the AI Act you are wishing for:

_____

_____

The AI Act foresees the setup of so called 'Regulatory Sandboxes' which are intended for 'trial and error', i.e. for implementing the AI Act "without being charged" when things go wrong. What are your expectations for such a Sandbox in your country? What kind of services, actors or waivers would you like to see there? Please elaborate

_____

_____

If you could change one thing in the AI Act. What would it be?

_____

_____

_____

_____

Would you like to receive the results of this survey?

- Yes

- No

Please enter your email address, if you'd like to receive the results.

_____

Appendix B: Questionnaire for VCs

(optional) What €-amount are you planning to invest in 2023?

Dropdown:

- < €10M
- €10 - €50M
- €50M - €100M
- €100M - €250M
- €250M - €500M

Do you think EU-based AI Startups are globally competitive?

- Absolutely - The vast majority is globally competitive
- Somewhat - More than the half are globally competitive
- Rather not - Less than the half are globally competitive
- No way - Hardly any is globally competitive

What share of the startups you hold equity in is using AI as part of their offering?

Dropdown:

- 10-20%
- 20-30%
- 30-40%
- 40-50%
- 50-60%
- 60-70%
- 70-80%
- 80-90%
- 90-100%

In a nutshell, the AI Act will regulate the development, marketing and usage of AI in Europe following a risk-based approach, meaning, the higher the risk of a AI System (low-risk, high-risk, prohibited) the stricter the regulatory requirements. High-risk AI covers safety-related applications across industries such as cars, airplanes, medical devices, or toys, but also certain areas of usage, including education, employment, law enforcement or critical infrastructure. Moreover, General Purpose AI Systems (AI used in diffent "contexts") might be classified as high risk (e.g. any Computer Vision startup that can apply their models to different use cases). High-risk AI needs to undergo a conformity assessment to meet requirements, e.g. on data governance, explainability, accuracy, cybersecurity and human oversight. Developers of high-risk AI face comprehensive obligations, too. When we asked startups, ~38% answered, they will be high risk and another ~17% answered they could potentially be considered as high risk.

Have you heard about the AI Act before?

- Yes
- No

The AI Act is anticipated to result in additional costs and benefits, see below:

Costs stem from the additional regulatory obligations and requirements:
- Need to conduct a Risk Classification per AI System
- Strict requirements for "high-risk" AI Systems (e.g. accuracy, robustness, cybersecurity, transparency, documentation, etc);
- Providers / Developers of
- "high-risk" AI Systems need to establish a Quality Management System, conduct a Conformity Assessment, and afix a CE-Mark to the AI System
- Some AI applications are prohibited in the EU (e.g. social scoring, predictive policing)
- Low risk AI is hardly/not regulated

Benefits stem from the increased level of trustworthiness:
- Compliant AI Systems bear a CE-Mark, recognized across Europe
- Higher Quality of the AI Systems in terms of accuracy, robustness, cybersecurity, etc.
- AI Development with the goal to protect health, safety and fundamental human rights
- Higher user acceptance due to improved transparency, human oversight and explainability

How is the AI Act likely to change the global competitiveness of EU-based AI Startups?

- Significantly increase
- Somewhat increase
- Remain about the same
- Somewhat decline
- Significantly decline
- Other: _____

Section: Investment behavior

As the AI Act is going to affect AI developments in the EU, in this section ask how it might change your investment behavior too.

Investment strategy: How is the AI Act going to influence what kind of AI innovation by EU-based AI developers will receive private investments?

With the AI Act, more investments will go into...

- Potentially disruptive AI Solutions with very unclear risk category (Reinforcement Learning, Advanced ML for BioTech, etc.)
- High-Risk AI Systems in with high-value in specific areas (Critical Infrastructure, Law Enforcement, Education, Employment)
- Large Foundation models and General Purpose AI (Language Models, Computer Vision Models, etc)
- Incremental Innovations with a defined use case (Adopters of AI Models, e.g. Marketing Startups with AI)
- Tool providers (e.g. data generation) or development infrastructure providers (e.g. MLOps)
- Other: _____

There are two major risk categories in the AI Act, which are assigned per AI Use Case / Application: High-risk (significant obligations) and Low-risk (little-no obligations). How do you consider the risk category in your investment decision?

- We would focus our investments on low-risk AI startups
- We your focus our investments on high-risk startups e.g. because it often comes with high-value

- The risk class does not play a role in our view
- We have not (yet) familiarized ourselves with the risk classes and their implications on our investment decisions

With the AI Act being on the horizon, do you consider moving investments?

- Invest more into AI startups in Europe
- Invest more into AI startups outside Europe
- Invest more into other (non-AI) startups in Europe
- Other: _____

Section: Risk and Return Profile of European Startups

If a startup falls into the "high-risk" Class in the AI Act, how does this affect the valuation and attractiveness of the startup?

Scale: Significantly increase - Somewhat increase - No change - Somewhat decline - significantly decline

- Likelihood of investment
- Investment amount
- Effort and transaction cost around Due Diligence
- Overall long-term return potential from investment
- Valuation of the startup

If a startup falls into the "low-risk" Class in the AI Act, how does this affect the valuation and attractiveness of the startup?

Scale: Significantly increase - Somewhat increase - No change - Somewhat decline - significantly decline

- Likelihood of investment
- Investment amount
- Effort and transaction cost around Due Diligence
- Overall long-term return potential from investment
- Valuation of the startup

Section: Recommendations

What is your recommendation to the policy-makers writing and voting on the AI Act?

_____

_____

_____

_____

_____

_____

What is your recommendation to EU-based AI Startups?

_____

_____

_____

_____

_____

_____

Are you interested in receiving the results of this survey?

- Yes

- No

If "yes", please provide your email address:

_____