

THE AI ACT: HELP OR HINDRANCE FOR SMEs?

An analysis of the cost of compliance
with the **AI Act** for SMEs

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TABLE OF CONTENTS

The regulatory framework	06
The Proposed AI Act	08
Revisions to the AI Act	14
Impact of the AI Act on SMEs	15
The methodology used by the IARR	15
IARR Methodology Review	20
Our proposed approach to estimating costs for SMEs	24
Scenario 1: Standard cost model (IARR) applied to SMEs	28
Scenario 2: Standard cost model using R&D value instead of AI market value	29
Scenario 3: An alternative approach	30
Our proposed approach to estimating benefits for SMEs	32
Achieving economies of scale: European Digital Innovation Hubs and their role	32
Scenario 3b: Alternative approach foreseeing potential benefit from EDIHs	34
Concluding remarks	36

EXECUTIVE SUMMARY

The technological development of artificial intelligence (AI) is proceeding rapidly, with investment in AI-based solutions dramatically increasing across the globe. **Europe is no exception.**

The European Commission has a clear strategy in place to foster digital transformation and recognises that innovation in digital technologies and AI brings tangible improvements to society but, at the same time, acknowledges that their associated risks must be taken seriously and properly addressed. In an effort to protect citizens' fundamental rights, digital space and AI are being increasingly regulated. It is within this context that, in April 2021, following the publication of the AI White Paper in February 2020, the European Commission proposed a regulatory framework on AI (the AI Act) to ensure fairness and trustworthiness of high-risk AI systems.

Increased regulation, while vital, can also result in higher costs of compliance for companies, especially for small-medium enterprises (SMEs), which may be less positioned to absorb these costs as are their larger counterparts.

The main objective of this paper is to estimate the costs that SMEs would face when achieving

compliance with the requirements of the AI Act. We believe that a better-regulated market is the only way to achieve AI that is trustworthy and fair. However, greater attention should be given to the European SMEs ecosystem, which will be the most impacted and can easily be crippled by high compliance costs.

Building on the seminal work of the "Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe" (IARR), we probed deeper into compliance costs for SMEs. Total costs calculated in the IARR include both compliance and conformity costs. The former are based on the assumption that all companies – with no distinction between AI providers and users – operate in a break-even market, and are thus calculated as a linear proportion of the total AI market value. Conformity costs are determined as the costs incurred by a company to obtain certification by an authorised body.

In this paper, we reviewed some of the assumptions for compliance cost calculation, and we aimed to model total cost on a general small-medium AI provider company, as per table below.

Value

Total revenues (Dec-2021)

€ 23.2 mln

AI R&D share

15% of total revenues (€ 3.4 mln)

Number of employees (Dec-2021)

150

Of which developers

50





Hence, three scenarios were developed to analyse the costs of compliance for SMEs. The first scenario adapts the IARR standard cost model to the modelled SMEs. Despite following the standard cost model approach, the second scenario calculates compliance costs on the basis of R&D value instead of the total AI market value. Scenario 3 provides an alternative approach whereby total costs are not calculated as a proportion of AI value, but rather, consist of software development costs and costs for compliance activities in relation to R&Ds. A fourth scenario (3b) builds on the assumptions of Scenario 3 and further includes cost savings for SMEs arising from the involvement of European Digital Innovation

Hubs (EDIHs) and Testing and Experimentation Facilities (TEFs).

Results of the analysis, summarised in the table below, show that if compliance costs are calculated using software subscriptions and actual activities, as in Scenario 3 – Alternative (€301,200), they are more than 10 times lower than costs calculated as a direct proportion of the AI market value (about €4 million in Scenario 1). When EDIHs and TEFs are included in the analysis (Scenario 3b), costs are expected to further drop (€229,444), as are the FTEs needed to comply with the requirements.

	Scenario 1 IARR	Scenario 2 R&D	Scenario 3 Alternative	Scenario 3b EDIH
Total costs for SMEs (€)	3,977,779	610,947	301,200	229,444
Total costs as % of revenues	17.3%	2.7%	1.3%	1.0%
FTEs	70.6	10.8	2.75	2.02

This paper provides an alternative approach to estimating compliance costs for a small-medium AI provider and represents a first attempt to analyse the impact the AI Act will have on SMEs. However, we believe that further research is needed to empirically validate the model here presented, thus helping achieve a better grasp on the actual costs SMEs will face.

As has been demonstrated in this paper, EDIHs and TEFs will play a significant role in mitigating the costs of compliance for SMEs when adhering to the AI Act requirements. A timely involvement of EDIHs and TEFs – through the development of common technological, legal, and management services – is

recommended to activate economies of scale and generate cost savings for SMEs when complying with the new requirements. Additional research on the benefits SMEs could enjoy from EDIHs and TEFs, would help make a stronger case for AI adoption.

We believe that a forward-looking perspective, which goes beyond the compliance costs, would increase SMEs confidence in embracing AI-based solutions that are fair and trustworthy.

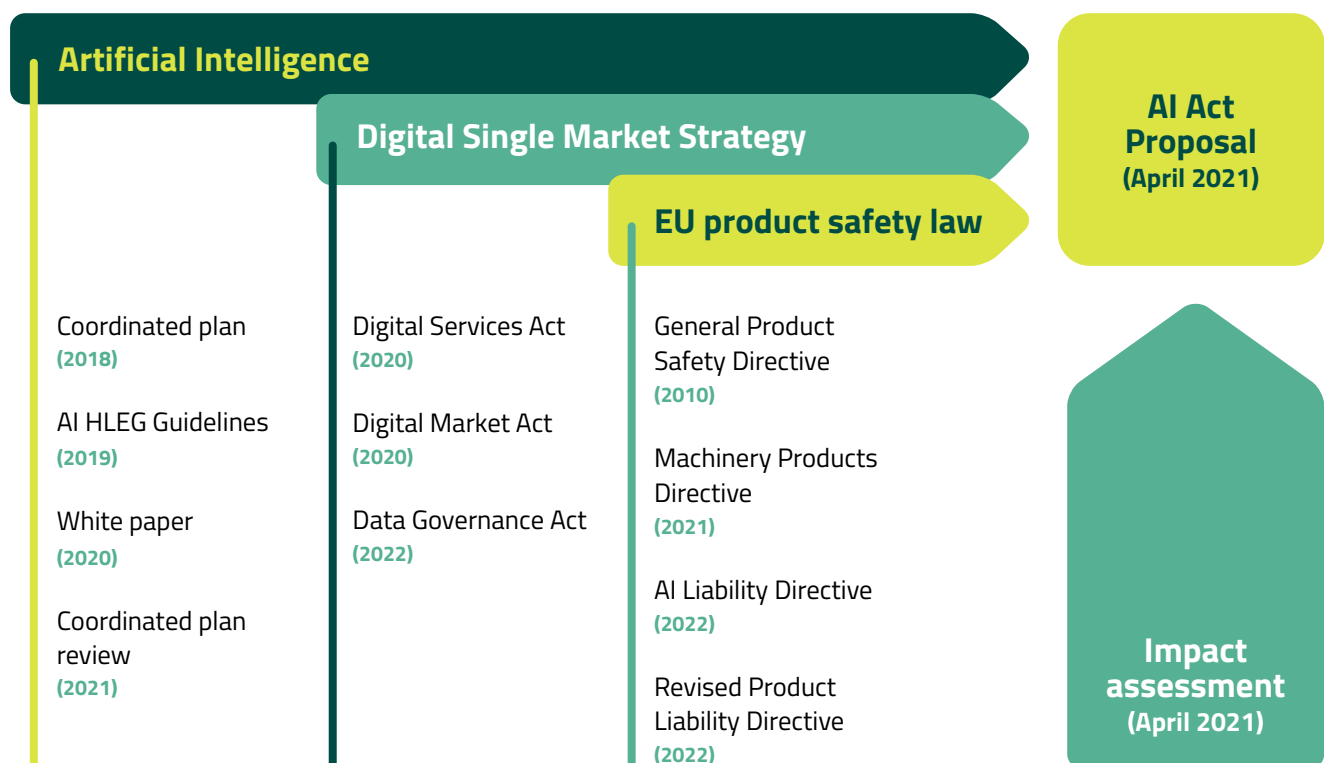
To this purpose, we suggest that a dedicated study, estimating benefits and valuating the actual impacts of the AI Act on SMEs, should be developed at European level.

THE REGULATORY FRAMEWORK

The European Commission (hereinafter the "Commission") has set the goal of making the EU a world class hub for AI while ensuring an appropriate ethical and legal framework. This framework is founded on the ideals that AI systems must be human-centric, trustworthy, and grounded in European values and fundamental rights.

To this end, the EU has a solid and balanced regulatory foundation on which to build, as well as the opportunity to set the global standard for a holistic approach to cutting edge technologies. The 2016 General Data Protection Regulation ensures a high standard of personal data protection and stands as an example for the way forward. Furthermore, in 2020, the Commission introduced the Digital Market Act Regulation, which, together with the Digital Services Act and the Data Governance Act, aims to provide a secure and fair regulatory framework for developing AI systems, while protecting the fundamental rights of users. The Commission has also been working on a series of communications, plans, strategies, and papers to advance toward a regulated and harmonised AI environment in Europe.

Figure 1 • Main regulatory activities that brought to the AI Act



Source: Authors' elaboration



The Commission's work on regulating AI was initiated in March 2018, with the establishment of the High-Level Expert Group on AI (HLEG) and the European AI Alliance. These efforts first materialised at the end of 2018 in the form of a Coordinated Plan on AI. Then followed the Ethics Guidelines for Trustworthy AI by the HLEG, which delineated the four ethical principles (strictly based on fundamental rights) and the seven key requirements that AI systems should meet to be deemed trustworthy. Published in February 2020, the White Paper on Artificial Intelligence aimed to outline a common definition of AI and analyse strengths, weaknesses, and opportunities for Europe in the global AI market. Building on these initiatives, the Commission published in April 2021 the revision of the Coordinated Plan on AI for the year 2021, proposing a concrete set of cooperative initiatives for the Commission and the Member States. The involvement of the Digital Innovation Hubs (DIHs) is also foreseen to strengthen Europe's leadership in AI, through their potential to increase cooperation and decrease costs for AI-uptake in SMEs. Together with the updated Plan, the Commission also published the **"Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence" (hereinafter the "AI Act Proposal")**, which stands as the first-ever legal framework on AI. Its main purpose is not only to promote the development of AI, but to forge a distinctly European market for AI differentiated from other global players for its level of trustworthiness — building Trustworthy AI in what has been deemed "The European Way". Legal certainty facilitates investment and innovation while addressing and mitigating the risks AI technologies pose to safety and fundamental rights. The Commission strongly believes that the only way to minimise the negative impacts of these technologies is through regulation, for which the AI Act Proposal also contains prohibitions and a conformity assessment system adapted from EU product safety regulations. Seeking to complement the AI Act Proposal, at the end of September 2022, the Commission adopted two proposals to adapt liability rules to the digital age: the AI Liability Directive and a revised Product Liability Directive. Focusing on the former, it aims to address characteristics of AI software which are considered challenging under current liability rules, specifically "opacity, autonomous behaviour and complexity". Liability law will form an important aspect of implementing AI regulation, as it provides a mechanism to determine who should be held responsible when AI malfunctions or causes harm.

THE PROPOSED AI ACT

With the goal of improving the functioning of the EU internal market, the AI Act Proposal is consistent with existing policy provisions in both the AI area and in the overall Digital sphere.

To ensure the uniform application of new rules and provide a clear and precise scope to all relevant stakeholders, the first draft of the AI Act Proposal suggested a common definition of AI systems: ***“artificial intelligence system” (AI system) means software that is developed with one or more of the following techniques and approaches:***

(a) machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;

(b) logic-and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

(c) statistical approaches, Bayesian estimation, search and optimization methods; and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with”.

This preliminary definition is currently under revision, as some view it as being unfeasibly wide for the purposes of AI regulation. However, such debates are fairly academic, as the operational impact of the AI Act Proposal is quite narrow, focusing only on high-risk AI systems and AI-embedded products or services. The common definition of “high-risk” AI is explored below.



TECHNIQUES AND APPROACHES:

Artificial Intelligence system' (AI system) means **software** that is **developed with one or more of the following techniques** and approaches and **can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions** influencing the environments they interact with.

Figure 2 • AI definition

Machine learning approaches

including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;

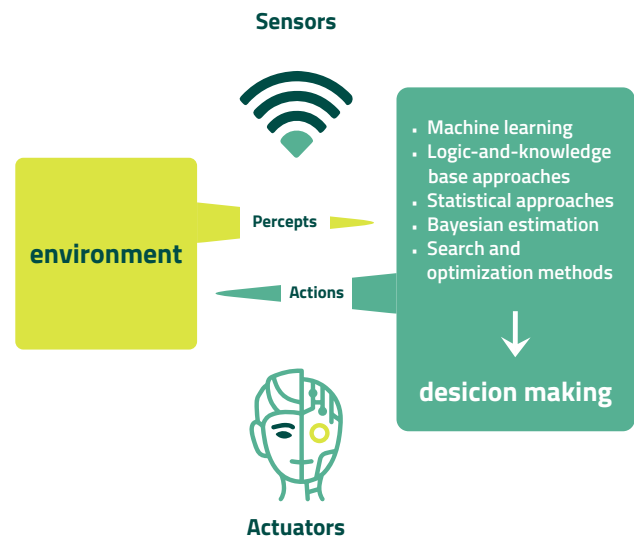
Logic- and knowledge-based approaches

including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

Statistical approaches

Bayesian estimation, search and optimization methods.

Source: Authors' elaboration



Source: EC, Proposal for a regulation of the European Parliament and of the council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence act) and amending certain union legislative acts

The reach of the AI Act Proposal, however, goes far beyond the borders of the EU. The Act will apply extraterritorially to any AI provider or distributor whose services or products reach and are used in the EU market. Therefore, its impact will be widely felt across the economy.

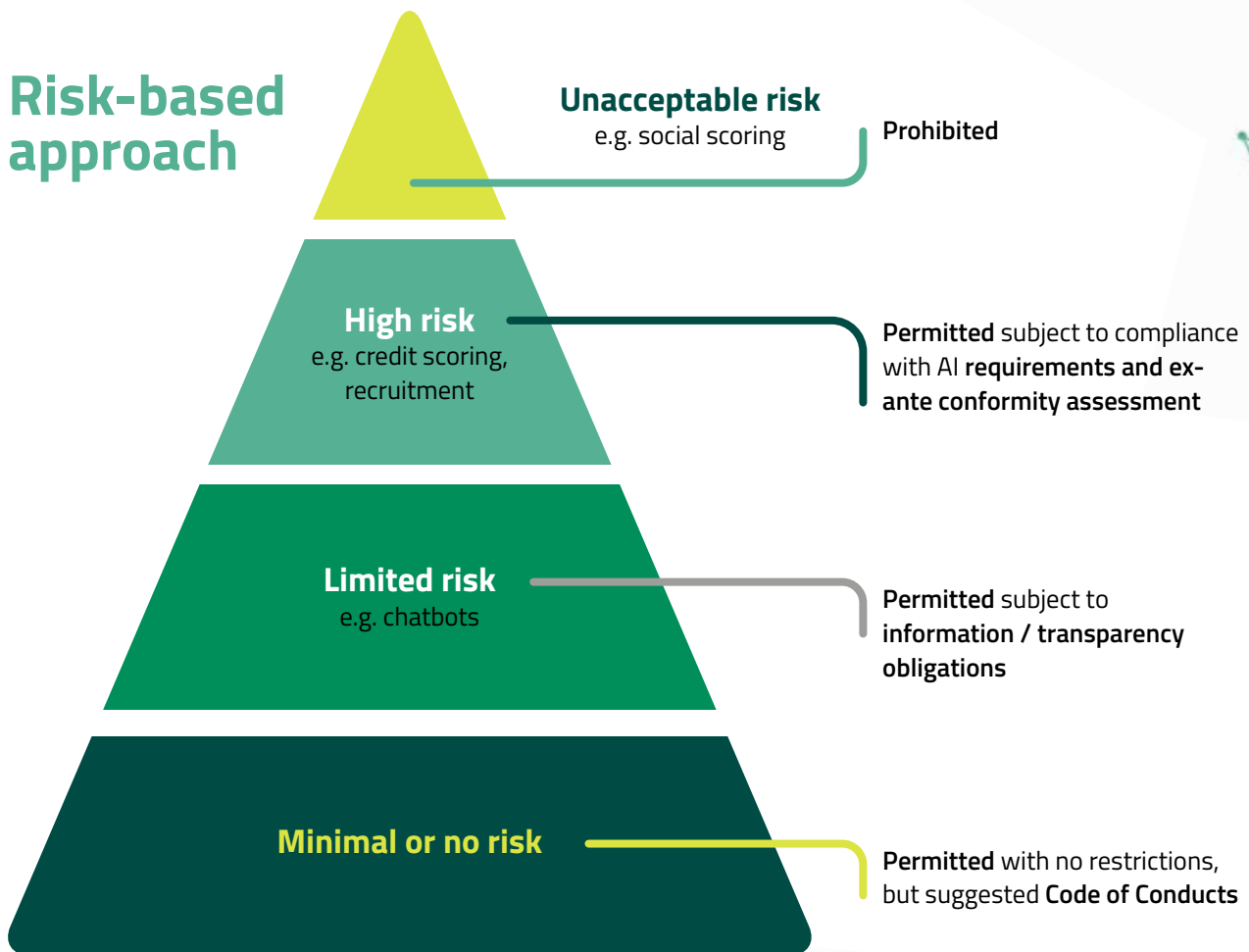
The primary entity subject to the regulation is the so-called “provider”, defined as “a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge. However, obligations apply to “users” as well, defined as “any natural or legal person using an AI system under its authority”. Obligations fall on importers and distributors (Articles 26–28) as in the product safety regime, with the intent of stopping dangerous products from entering the EU.

To design a proportionate, tailor-made, effective, and binding set of rules, the regulation followed a risk-based approach, differentiating between uses of AI that create: **i)** unacceptable risks (Title II); **ii)** high risks (Title III) and **iii)** limited risks (Title I). While AI practices associated with unacceptable risks are prohibited, those posing minimal risks are not subject to regulation. Below, Figure 3 summarises the Commission’s approach.

AI practices associated with limited risks are those related to systems that interact with humans (i.e., chatbots), emotion recognition systems, biometric categorisation systems, and AI systems that generate or manipulate visual, audio, or video content (i.e., deepfakes). Member States and the Commission merely “encourage” such providers to adhere to voluntary codes of conduct.

Figure 3 • Risk-based approach

Risk-based approach



Source: Authors' elaboration

Who is subject to the AI Act?

It will apply to any AI provider, user, importer or distributor whose services or products reach the EU market:

- **Provider:** any natural or legal person, public authority or other body that develops an AI system, or has an AI system developed
- **User:** any natural or legal person using an AI system under its authority

Potential **penalties** for non-compliance (from 2 to 6% of annual worldwide turnover) calculated based on the actual infringement (gravity, impact, etc.).



AI practices associated with limited risks are those related to systems that interact with humans (i.e., chatbots), emotion recognition systems, biometric categorisation systems, and AI systems that generate or manipulate visual, audio, or video content (i.e., deepfakes). Member States and the Commission merely “encourage” such providers to adhere to voluntary codes of conduct.

The scope of the legislation thus focuses on AI practices associated with high risks, which could adversely impact people’s safety or their fundamental rights. The proposal considers two types of high-risk AI systems:

1

High-risk AI systems used as a safety component of a product

or as a product falling under the Union Health and Safety Harmonisation legislation (e.g., toys, aviation, cars, medical devices, lifts).

2

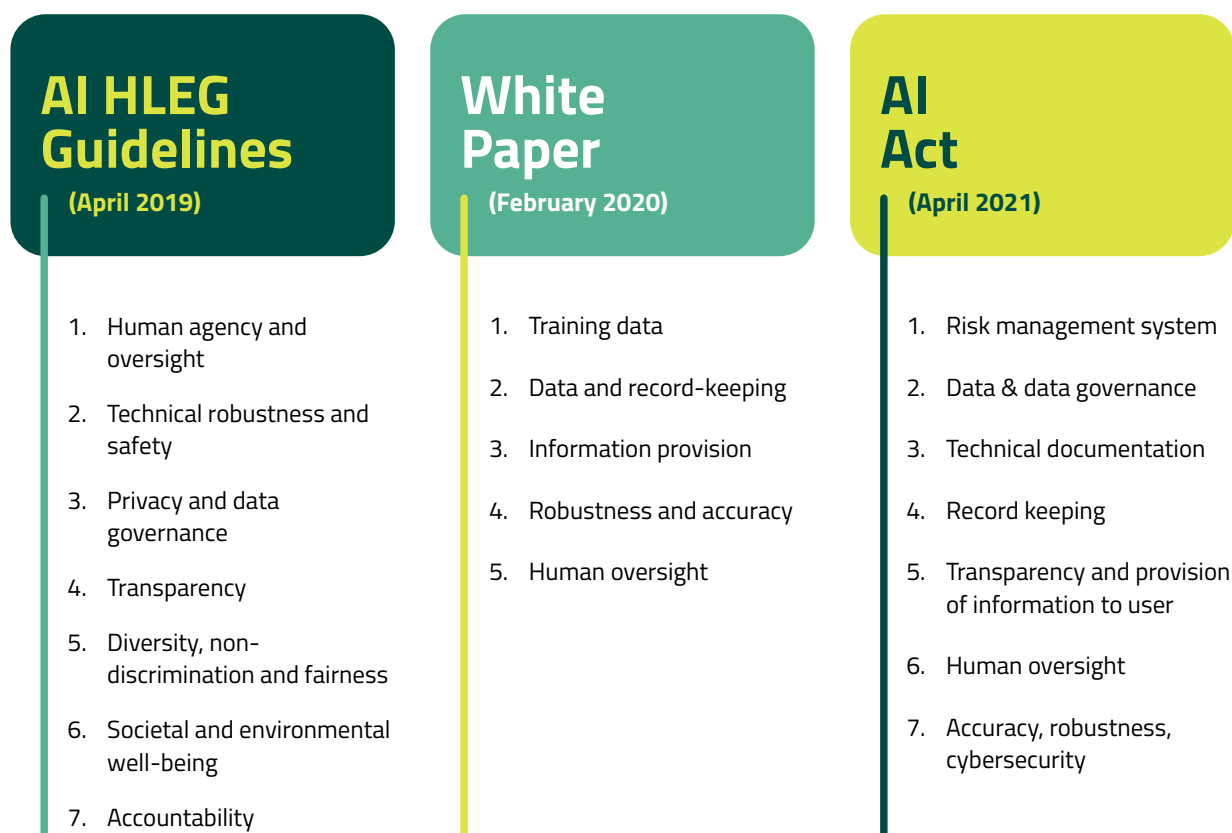
High-risk AI systems deployed in eight specific areas:

- Biometric identification and categorisation of natural persons;
- Management and operation of critical infrastructure;
- Education and vocational training;
- Employment, worker management, and access to self-employment;
- Access to and enjoyment of essential private services and public services and benefits;
- Law enforcement;
- Migration, asylum, and border control management;
- Administration of justice and democratic processes.

The AI Act Proposal contains an extensive list of essential requirements which is connected to the obligations of the regulated actors. Most of the obligations nevertheless fall on the “provider”. The seven proposed minimum requirements are derived from the 2019 Ethics Guidelines for Trustworthy AI by the HLEG.

TRUSTWORTHY AI REQUIREMENTS

Figure 4 • Trustworthy AI requirements



Source: Authors' elaboration

The AI Act Proposal introduces a sophisticated 'product safety framework' constructed around a set of four risk categories. It imposes requirements for market entrance and certification of high-risk AI systems through a mandatory CE-marking procedure which indicates that EU safety, health and environmental protection requirements have been met. The AI Act Proposal seeks to codify the high standards of the EU trustworthy AI paradigm - which requires AI to be legally, ethically and technically robust - while respecting democratic values, human rights and the rule of law. Continuity between the AI Act Proposal and existing legislation is ensured, thus the applicability of requirements deriving from the proposed AI Act should not affect the specific logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. The AI Act Proposal is complemented by

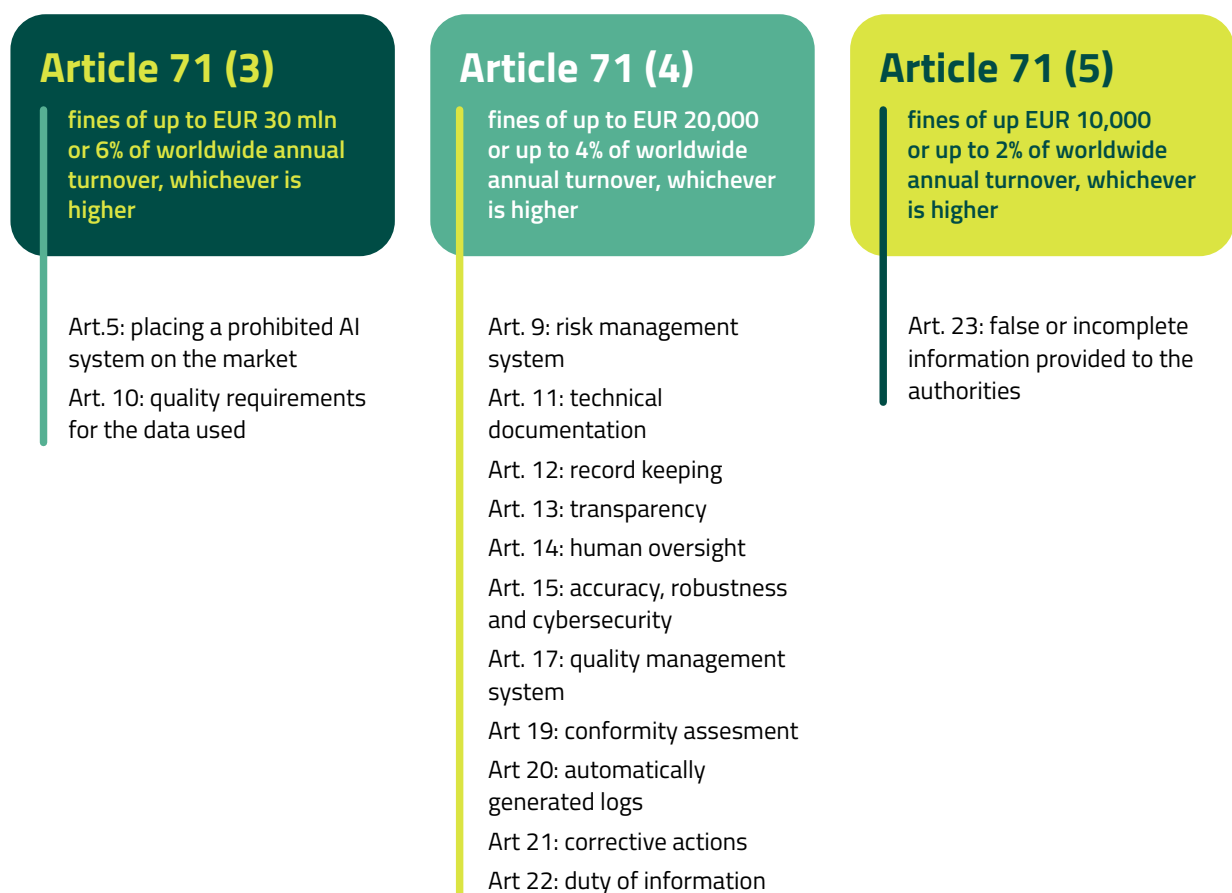


many further regulations which touch several areas of the European economy. For example, requirements in the forthcoming Machinery Regulation will reinforce the security of machinery by providing for the safe integration of AI systems in industrial equipment, thus complementing the safety risk requirements already covered by the AI Act Proposal.

How does the EU intend to enforce compliance with this new regulatory framework? Any subject found non-compliant with the regulation will incur sanctions. Article 71 of the Act provides for a three-level sanction concept, which includes different fines depending on the severity of the infringement as shown in the figure 5.

ADMINISTRATIVE FINES WITH THE RELATIVE INFRINGEMENTS

Figure 5 • Summary of administrative fines



Source: Authors' elaboration

In compliance with the terms and conditions established in the AI Act Proposal, Member States shall codify rules on effective, proportionate, and dissuasive penalties applicable to infringements of the regulation, including administrative fines. The AI Act Proposal also stipulates that Member States shall take all measures necessary to ensure such rules and penalties are properly and effectively enforced. Following the proposal of the AI Act in April 2021, the Commission envisions the second half of 2024 as the earliest point at which the AI Act could become applicable to operators with standards ready and the first conformity assessments carried out.

REVISIONS TO THE AI ACT

Following the publication of the AI Act Proposal, the Commission collected various feedback from a wide range of stakeholders who expressed their opinions on the proposed text. As of October 2022, the proposal is currently under discussion by the European Parliament and the Council. In Parliament, discussions are led by the Joint Committee on Internal Market and Consumer Protection (IMCO) and the Committee on Civil Liberties, Justice and Home Affairs (LIBE) and a vote on the final version of the AI Act is scheduled for November 2022. With regards to the Council, both the Slovenian Presidency and the French Presidency have provided revised versions of the proposed AI Act, reflecting consultation with and deliberation by the Member States and other actors.

In the “Presidency Compromised Text” published by the Slovenian Presidency, specific exemptions to the proposed legislation were proposed in matters such as National Security, Research and Development and General-purpose systems. The revision also extended the prohibition of AI uses to Private Sphere Social Scoring and Socio-Economic Vulnerability, and it included AI systems used in insurance as “High-Risk”.

The subsequent French Presidency proposed more significant changes: for example, they proposed modifying the sanctioning regime of the AI Act Proposal, and changing penalties to consider the size of companies. Under this revision of the French Presidency, if SMEs and start-ups were to engage in the unlawful use of prohibited practices (such as social scoring), they would face a maximum fine of 3% of their annual turnover. The maximum fines for larger companies, on the other hand, would reach 6% of their annual turnover. In addition, the French Presidency argues that sanctions should be subject to transparent procedural safeguards.

The revisions of the French and Slovenian presidencies, if implemented, would contribute to potentially reducing the cost of adoption of and compliance with the AI Act Proposal. On the other hand, some of these revisions would limit the scope of the AI Act Proposal, since the regulation would be only applicable to a narrow definition of AI.

As of early November 2022, the Czech Republic holds the Presidency and presented a final version of the compromise text. An harmonised proposal on the AI Act is expected at the beginning of December, with tripartite meetings between Parliament, the Council and the Commission to follow thereafter.

IMPACT OF THE AI ACT ON SMEs

The main objective of this paper is to estimate the cost of compliance for SMEs with requirements of the AI Act Proposal. As a basis, we provide a review of the **“Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe”** (hereinafter IARR). Building on the key findings of the IARR, our analysis will focus on SMEs, with the aim of delving further into the actual cost of AI development to arrive at a better estimate of the adoption costs associated with the proposed AI Act.

Our thesis – corroborated by empirical experience with SMEs – is that there could be significant opportunities to activate economies of scale and scope for SMEs adopting AI technology, which **(a)** generates cost savings within the SMEs ecosystem, and **(b)** increases confidence in embracing AI-based solutions.

The methodology adopted in the IARR for the impact cost calculation concerning the AI Act Proposal adoption is presented in the next section, followed by an alternative approach to estimating costs for SMEs. Finally, we provide the main benefits and recommendations on how SMEs may streamline their compliance with the requirements of the AI Act following its adoption.

THE METHODOLOGY USED BY THE IARR

This section provides a summary of the methodological approach followed by the IARR in the preparation of the study supporting the impact assessment for the adoption of the AI Act Proposal. The impact assessment prepared by the Commission follows the “Better Regulation” principles specified in the Toolbox and Guidelines documents.¹

As such, four different policy options² are assessed and evaluated against socio-economic impacts and impacts on fundamental rights. The IARR support study, in line with the AI Act Proposal, focuses on one of the four policy options proposed in the White Paper on Artificial Intelligence³: namely, the policy option 3+ “Horizontal EU legislative instrument following a proportionate risk-based approach”. It envisages a **regulatory framework for only high-risk AI systems, with the possibility for providers of non-high-risk AI systems to follow an optional code of conduct**. The study’s key assumptions for calculating the cost impact of the adoption of the AI regulation are six and hereafter summarised.

¹ https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

² The European Commission in the White Paper identified four policy options to achieve the general objective of the AI Act proposal

Policy options are summarised as follows:

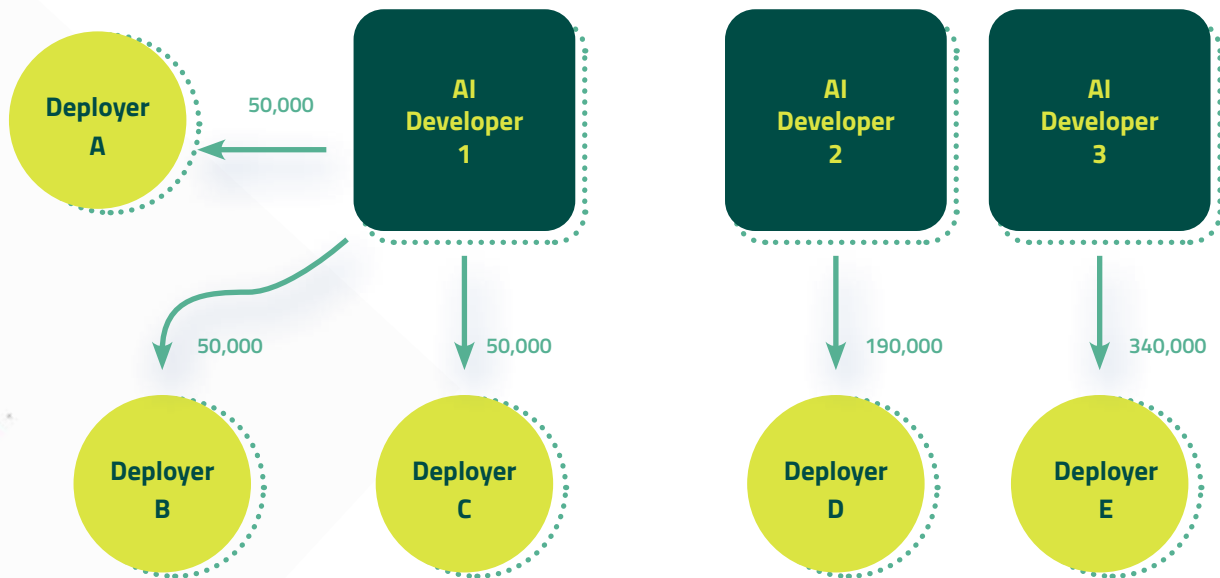
- I Option 1: EU legislative instrument setting up a voluntary labelling scheme;
- II Option 2: a sectoral, “ad-hoc” approach;
- III Option 3: Horizontal EU legislative instrument following a proportionate risk-based approach;
- IV Option 3+: Horizontal EU legislative instrument following a proportionate risk-based approach + codes of conduct for non-high-risk AI systems;
- V Option 4: Horizontal EU legislative instrument establishing mandatory requirements for all AI systems, irrespective of the risk they pose.

³ White Paper on Artificial Intelligence: a European approach to excellence and trust | European Commission (Europa.eu)

a

The study assumes that developers compete in a **break-even market**, where sales prices are equal to development costs, as in the following example reported in the report:

Figure 6 • Value of the market size of AI with 3 developers and 5 deployers



Source: European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report, Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

The figure depicts an economy consisting of three AI developers and five AI deployers.

Developer 1 constructs an AI system and sells it to three deployers at € 50,000 each.

Developer 2 creates a customised AI system for deployer D at € 190,000.

Developer 3 instead builds a very advanced, customised AI system that costs € 340,000.

b

The value of a so-called **"AI Unit"** is defined as the average development cost of an Artificial Intelligence application. An "AI system" will consist of one or more AI Units. The value of an AI Unit is set at € 170,000.

Considering the presumptions a) and b) above, it follows that the value of the market size of AI - defined as the amount of spending by customers in the market - is thus €680,000. The assumption is that the regulation would only apply to products sold directly to end users by providers. As a result, the IARR focuses exclusively on compliance and conformity tests necessary for providers. A remaining scenario for consideration is, therefore, the compliance journey that users would need to follow if they were to buy AI applications from providers and subsequently customise them.

C

The compliance cost assessment provided by the study is based on the Standard Cost Model (see Figure 7) featuring standardised tables with time estimates per administrative activity and level of complexity (as proposed by the German Federal Government). The cost estimation is built on time expenditures for activities linked to the five requirements present in the AI Act Proposal (see Table 1), and the **total compliance cost** is determined as **€29,276 per AI Unit**.

Table 1 - Compliance cost of all 5 requirements per AI unit

	Training data	Documents and record-keeping	Information provision	Human oversight	Robustness and accuracy	TOTAL
Administrative activities by level of complexity ⁴						
Familiarisation with IO	9	5	10	1	3	28
Procuring data	3		6		1	10
Filling in forms, labelling, classifying	2	2	3			7
Performing calculations	2				2	4
Checking data and inputs	6	2	1		2	11
Correcting errors	3	1			2	6
Processing data	5	3	3		2	13
Transmitting and publishing data		3	9			12
Internal meetings	5		6	1	3	15
External meetings		1	3	1	1	6
Payment						
Photocopying, filing, distribution						
Cooperating with audit by public authorities		1				1
Corrections following audit						
Procuring additional information in case of audit		1				1
Training courses	1	1	1	1	2	6
Total minutes	5,180.5	2,231	6,800	1,620	4,750	20,581.5
Total admin cost (hourly rate = € 32)						€ 10,976.8
Additional costs						
Procuring goods and services	Purchasing additional data (€ 500) + additional legal advice					
Procuring services and/or hiring additional staff						
Supervisory measures	Security testing services (€ 5,000) - 0,2 FTE staff – € 12,800/year					
Total cost						€ 29,276.8

Source: Authors' elaboration of European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report, Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

⁴ The figures below represent the level of complexity for each activity. According to the German Federal Government tables, the level of complexity is then translated into number of minutes required for each activity. Activities of higher complexity will require more minute to be completed and will be more costly

d

To obtain the **total compliance cost value** for the EU Artificial Intelligence market, the total AI market size is first determined - using as sources reports from the Allied Market Research⁵ and Grand View Research⁶ and then divided by the value of the AI Unit (see Figure 7). The result is then multiplied by the compliance cost per AI Unit (see Table 1). The result is summarised in the table below.

Figure 7 • Standard Cost Model

$$\text{Total compliance cost} = \left(\frac{\text{Value of the European Ai market}}{\text{Value of an AI unit}} \right) \times \text{Cost per AI unit}$$

Source: European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report. Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

Table 2 • Total compliance costs EU AI market, no BAU considered (EUR million)

100% coverage	2020	2021	2022	2023	2024	2025
EU (high)	1,849.08	2,660.90	3,829.08	5,510.12	7,929.23	11,410.34
EU (low)	598.17	930.74	1,448.20	2,253.41	3,506.33	5,455.83

Source: European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report. Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

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A correction factor - called **Business As Usual or BAU** - is then applied to the compliance cost value to take into account the maturity of the various markets (e.g., IT, Finance, Insurance, Manufacturing, etc.) concerning the adoption of new regulations (e.g. GDPR) and the level of data usage (data intensity index). A higher level of maturity in certain activities implies that the compliance costs to the new regulation will be lower. Accounting for level of maturity by sectors, the resulting total compliance costs are summarised in the table below.

Table 3 • Total compliance costs EU AI market, BAU considered (EUR million)

100% coverage	2020	2021	2022	2023	2024	2025
EU (high)	1,674.40	2,409.33	3,451.48	4,787.68	6,299.32	7,260.70
EU (low)	541.66	842.75	1,305.39	1,957.96	2,785.58	3,471.69

Source: European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report. Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

⁵ Artificial Intelligence Market Size, Share | Forecast - [2021-2030] ([alliedmarketresearch.com](https://www.alliedmarketresearch.com))

⁶ Artificial Intelligence Market Worth \$1,811.8 Billion By 2030 ([grandviewresearch.com](https://www.grandviewresearch.com))



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The AI-embedded product or AI system must also pass a conformity assessment by a notified body. The **cost of the conformity assessment procedure** is determined as the cost of both obtaining certification by a notified body in the dual scenario of EU-type examination and adhering to full quality assurance with a Quality Management System solution (QMS). The sum of in-house cost and cost to notified body are represented in the table below, computed per each activity.

Table 4 • Conformity cost estimates

	Developing technical file (hour)	In-house costs (EUR)	Review of technical documentation (hour)	Testing (hour)	Audit (hour)	Total minutes (hour)	Total cost to notified body (EUR)	
Training data	15	480	4		10	14	4,000	
Record keeping	15	480	4		4	8	2,800	
Information provision	15	480	2			2	400	
Human oversight	15	480	2	4		6	1,600	
Robustness and accuracy	15	480	4	15		19	5,600	
Total costs €		2,400					14,400	16,800

Source: European Commission, Directorate-General for Communications Networks, Content and Technology, Renda, A., Arroyo, J. Fanni, R., et al., (2021). Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe: final report Publications Office of the European Union <https://data.europa.eu/doi/10.2759/523404>

Finally

Regarding the possible impact of the adoption of the regulation by SMEs, the IARR focuses primarily on benchmark values for GDPR adoption, testing activity, and conformity assessment cost. Thus, this paper seeks to build upon the IARR study in providing a methodology to calculate a precise cost figure for SMEs following the adoption of the AI Act.



IARR METHODOLOGY REVIEW

The AI Unit value

The cost of developing a software product for a software developer is not included in the AI Unit value.

Before discussing the assumptions behind the AI unit value, it should be noted that the IARR distinguishes between two main categories: AI developers and AI deployers. Slightly diverging from the definitions in the AI Act Proposal, developers (providers) are those entities developing and selling AI software or systems, while deployers (users) are the organisations which develop customised AI applications or purchase them from a third-party. Given that the AI Act Proposal is the most recent document, we will use “providers” and “users” for this paper. The table below reports the key sources and assumptions considered in the IARR study to calculate the value of an AI unit.

Table 5 - AI Unit value

WEBFX⁷

- 1 Custom AI solutions cost: \$6000 - \$300,000 per solution
- 2 Third-party AI software cost: \$0 - \$40,000 per year
- 3 Ongoing AI services, like consulting, depending on the consultant's hourly fee
(most AI consultants charge \$200 to \$350 per hour)
- 4 In-house management costs more than outsourced AI management

AZATI.AI⁸ Six project phases:

- 3 Discovery & analysis: included
- 4 Data collection & preparation: included, except for specific cases that require additional efforts
- 5 Prototype implementation & evaluation: starting from \$2,500
- 6 MVP: $\$8,000 < x < \$15,000$
- 7 Product release: $\$60,000 < x < \$100,000$ (based on Azati past use cases)
- 8 Maintenance & support:
Factors that affect overall costs: data-related issues (e.g., lack of suitable data) and/or performance-related costs (e.g., processing algorithms performance)



Both WebFX and Azati.ai consider how much it might cost a user to develop a customised AI application or purchase it from a third-party organisation (provider). On the other hand, the cost of developing a software product by a software provider is not directly considered. In fact, in the case of purchase from a third-party organisation, the cost indicated by WebFX is not representative of the actual development cost, since software products are typically sold as Software-as-a-Service (SaaS) and, consequently, the price paid by the buying organisation is an annual fee. As mentioned above, the AI Act Proposal clearly delineates the compliance process and the conformity assessment for AI providers. However, it does not specify compliance procedures when it comes to users buying AI applications from providers. As described in the IARR, the most likely scenario is that users will have to conduct testing and subsequently receive certification from the provider. On the contrary, if users develop everything in-house, they would be considered as providers and would follow their same process. With regards to compliance cost, we acknowledge that development cost is probably not the best predictor and alternative indicators should be considered. A list of more adequate indicators is provided below:

- Number of data sources used by the specific AI application
- Training data volume
- Type of data
- Number and type of algorithms used by the AI application
- Number of end-users

However, information on the indicators listed above is extremely difficult to find at this stage. As a result, for some of the scenarios of an alternative cost impact assessment for SMEs, we adhere to the assumptions proposed by the IARR of the AI Unit value equals to € 170,000 and consider it as a rough approximation to calculate the number of AI Units.

⁷ WebFx (AI Pricing | How Much Does Artificial Intelligence Cost in 2020? (webfx.com))

⁸ How much does artificial intelligence (AI) cost in 2021? - Azati: Uniting experts to fulfil important projects



The break-even market hypothesis

The break-even market hypothesis and the use of total AI market size can be misleading when calculating the total cost impact

Assuming a break-even market means that only development costs are covered. However, the total market size value also includes software, professional services, and customer services, in the case of the Grand View Research Report, and similarly, hardware, software, professional services, and customer services in the case of the Allied Market Research Report. According to the standard cost model formula, (Figure 7), compliance cost is directly proportional to the value of the AI market. Since the correlation between professional services, customer services, hardware turnover, and the compliance cost value is not significant, our suggestion is to consider the R&D investment instead of the total AI market value in the standard cost model formula. Using R&D investment would, in turn, enable a more precise estimation of costs. The correlation between R&D and compliance costs is depicted in the figure below (Figure 8), in which different AI Act Proposal requirements are mapped against each development lifecycle (R&D) phase for an AI application.





The total cost

Total compliance costs do not include costs for risk management systems since the IARR predated the AI Act Proposal.

It is likely that actual costs are underestimated in the IARR, as both one-off costs (i.e., costs to establish and implement a risk management system) and recurring costs (i.e., costs to document and maintain a risk management system) are not considered. Having recognised this, the estimation of risk management compliance costs remains outside the scope of our analysis. In order to preserve the comparability of our findings with IARR estimates, risk management costs are also excluded from our approach.

We found that, overall, the IARR doesn't provide a specific approach for estimating the impact of the AI Act Proposal on SMEs and assessing consequent compliance costs. Regarding conformity costs, a specific proxy is used to assess these costs for SMEs. However, this estimate is limited to Quality Management System costs. European SMEs are already "on the back foot", due to a lack of investments and data access, and therefore strain to make their voice heard.⁹⁻¹⁰

The European Digital SME Alliance argues that the EU should pay more attention to fostering AI innovation by strengthening the AI ecosystem while supporting the digital frontrunners, namely, SMEs and start-ups that develop and provide AI solutions.

For these reasons and more, we believe that further insights and recommendations are required to estimate the impact of the AI Act Proposal on SMEs. In this paper we attempt to improve the existing analysis by providing alternative approaches, as described in the sections below.

⁹ <https://www.digitalsme.eu/digital/uploads/DIGITAL-SME-Position-Paper-AI-Act-FINAL-DRAFT-1.pdf>

¹⁰ <https://www.digitalsme.eu/digital/uploads/AI-Open-Letter-2022.pdf>

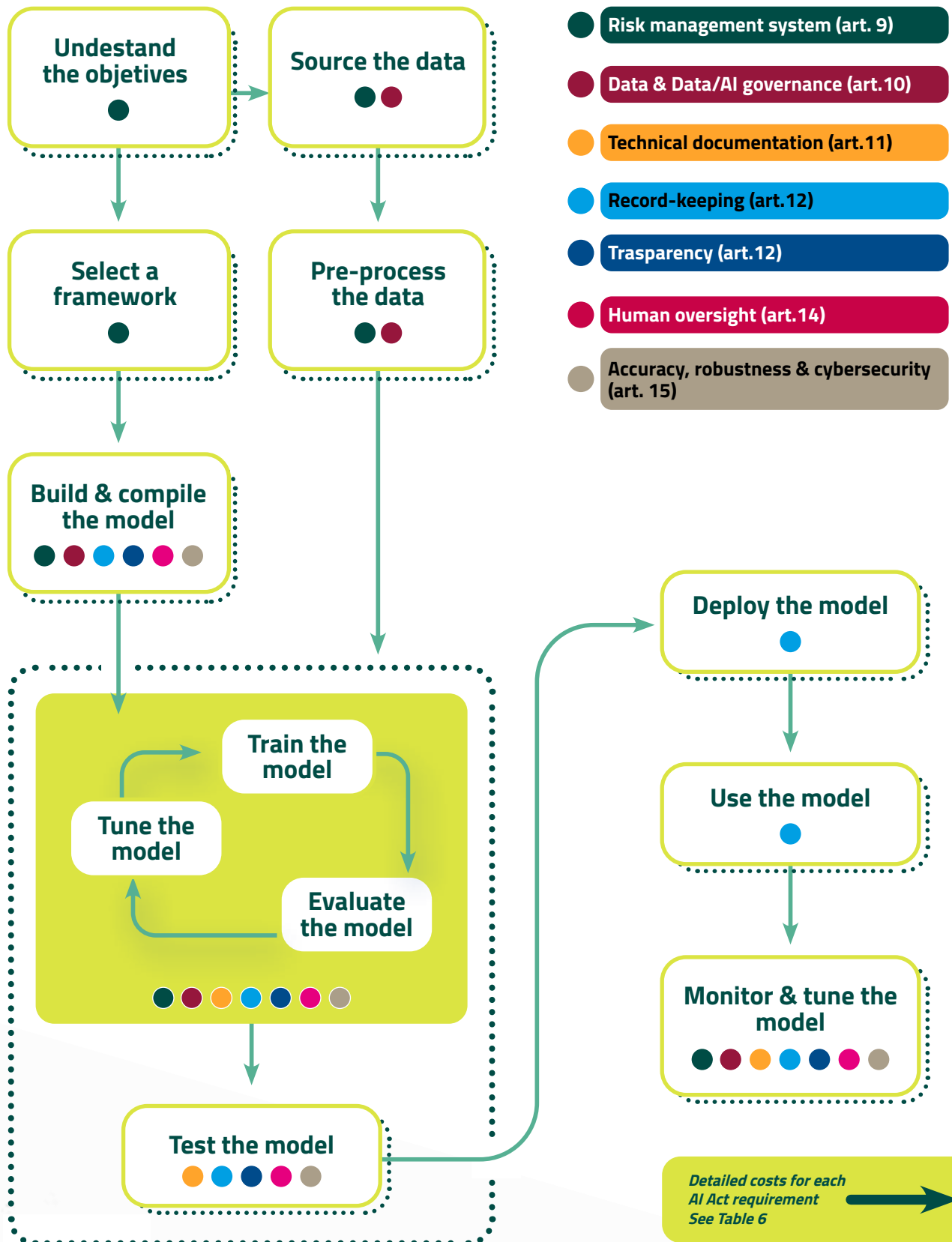
OUR PROPOSED APPROACH TO ESTIMATING COSTS FOR SMEs

It is recognised that a precise estimation of total costs to comply with AI Act Proposal requirements is still challenging, especially for SMEs for whom data are often not available. Our aim in this section is to **define a theoretical model to calculate compliance costs for SMEs** and to corroborate the findings with the development of an empirical example. The validity of the proposed approach presented below has been peer reviewed and tested with several SMEs.

The AI Act Proposal provides seven requirements with which all high-risk AI systems must comply. Before calculating the costs, we crosschecked the activities of the development lifecycle against the requirements to better grasp what complying with the requirements would entail. The development lifecycle is depicted in the figure below. The tags represent additional costs (both one-off and recurring costs) AI providers will bear to comply with the new regulation.



Figure 8 • Development lifecycle phases and AI Act requirements



Source: PD ISO/IEC TR 29119-11:2020, Software and systems engineering Software testing-Part 11: Guidelines on the testing of AI-based systems

In the figure above, the AI Act Proposal requirements are mapped against the development lifecycle phases of an AI system. In order to depict actual costs of each requirement, a more detailed description of potential one-off and recurrent costs for each phase is provided below.

Table 6 - Detailed costs for each AI Act requirement

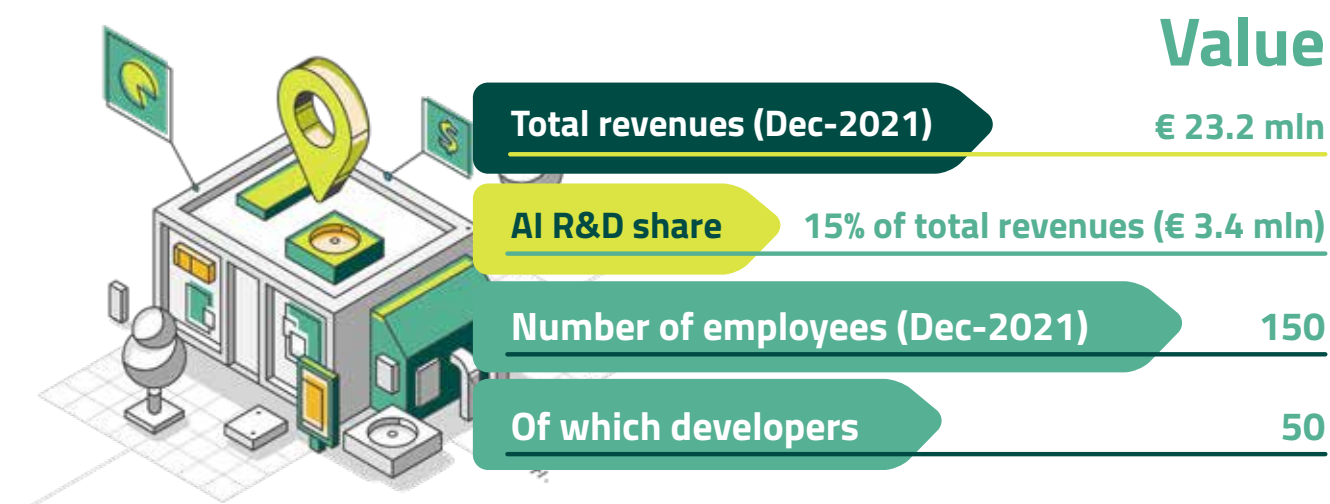
Development lifecycle phase	AI Act requirements	Cost typology
Throughout the entire lifecycle of an AI system	Risk management system (art.9)	One-off: Establishment, Implementation Recurrent: Risk management activities, monitoring costs
▪ Select a framework ▪ Source the data ▪ +Pre-process the data	Data & Data/AI governance (art.10)	One-off: Designing and implementing Data & AI governance solutions Recurrent: Data & AI governance tools fees, Data & AI governance activities
Throughout the entire lifecycle of an AI system	Technical documentation (art.10)	Recurrent: Drawing up the tech documentation, familiarisation with new requirements, updating technical documentation
	Record-keeping (art.12)	One-off: while designing the system, including logging capabilities Recurrent: keeping documentation on the functioning of the AI system
▪ Build and compile the model ▪ Train the model ▪ Tune the model ▪ Evaluate the model ▪ Test the model ▪ Deploy the model ▪ Use the model ▪ Monitor & tune the model	Transparency and provision of info to users (art.13)	Recurrent: Designing and implementing transparency solutions, keeping documentation on the functioning of the AI system
	Human oversight (art.14)	Recurrent: Designing and implementing human oversight processes and solutions, keeping documentation on the functioning of the AI system
	Accuracy, robustness & cybersecurity (art.15)	Recurrent: Designing and implementing accuracy, robustness & cybersecurity solutions, keeping documentation on the functioning of the AI system

Source: Authors' elaboration

Although the breakdown of cost provided above is necessary to calculate the effort envisaged to comply with the new requirements, an in-depth analysis of these costs goes beyond the scope of this paper.

The next sections will provide various scenarios developed to estimate the impacts of the proposed AI Act Proposal on SMEs. As SMEs are the focus of this analysis, we will base the calculation on a real-case modelled example. The table below presents the features of a representative SME **developing AI solutions** (Provider). The 'use case' has been elaborated by the authors and peer-reviewed by our digital SMEs network.

Table 7 • SME use case



Source: Authors' elaboration

The values modelled for representative SMEs with the characteristics defined in Table 7, will be used in all calculations developed below.



SCENARIO 1:

Standard Cost model (IARR) applied to SMEs

In this scenario, we attempt to calculate the impact of the proposed AI Act Proposal on SMEs following the standard cost model approach provided by the IARR and using data from real-life case examples of European SMEs that are AI providers.

Approach

In this scenario, we maintain almost every assumption of the IARR. The study estimates the value of one AI unit at € 170,000, and it calculates the number of AI units by dividing the total AI market value by the value of one AI unit. Therefore, to estimate the number of AI units that a provider develops in one year, we divide the total revenue of a representative European SME by € 170,000. Then, following the standard cost model of the IARR, we multiply the number of AI units obtained for the compliance cost of one unit of AI, which, per IARR calculations, equals € 29,276.80. To this value, we add conformity costs computed by the IARR, which are estimated at € 16,800.

Calculation

Using the formula provided in the IARR, the calculations are the following:

$$\text{Total costs} = \left(\frac{\text{Total revenue}}{\text{AI unit value}} \right) \times \text{compliance cost of AI unit} + \text{conformity costs}$$

$$\text{Total costs} = \left(\frac{€ 23.2 \text{ mln}}{€ 170 \text{ k}} \right) \times € 29,276.80 + € 16,800 = € 4 \text{ mln}$$

The total costs in Scenario 1, modelled on a representative SME, equal **about 4 million**.

Insights

Following the assumptions and cost model of the IARR, the total costs modelled to the typical SME equal 17.3% of total revenues.

Moreover, based on the number of AI units obtained (136,5) and the total minutes of activity needed to reach compliance provided by the IARR (20,852), total costs can be expressed in about 71 FTEs ¹¹. **We believe that this scenario would be hardly feasible for SMEs and result in a definite barrier to (the future regulated) market entry.**

¹¹ FTEs = Total costs / Average hourly rate / Number of hours in a day / Number of days in a year. Building on the IARR assumption, FTEs are calculated considering an average hourly rate of € 32, 8 hours per day and 220 days per year. In scenario 1, a modelled SME would require 124,00 hours (€ 3.9 mln / € 32) and 15,500 days (124,300 / 8) resulting in 71 FTEs (15, 537 / 220) to cover activities to comply with requirements

SCENARIO 2:

Standard cost model using R&D value instead of AI market value

In the second scenario, we maintain the approach provided by the IARR, although with the addition of one significant assumption: the number of AI units is calculated by dividing the R&D value by the AI unit value. As detailed above, we assumed it would be more accurate to use the value of R&D rather than the total revenues.

Approach

Similar to Scenario 1, we maintain the IARR estimates for the value, the compliance cost and the conformity costs for one unit of AI. However, to more accurately compute the number of AI units, we divide the **value of R&D of the representative SME by the value of one unit of AI. The value of R&D is assumed as a percentage of the annual revenues**, and, according to the evidence collected, it is reported that R&D for a company developing AI systems ranges between 8% and 18%. For the purpose of this study, it is assumed that R&D represents 15% of the total revenues. It is also assumed that AI **providers have all AI governance tools and infrastructure in place** to comply with the requirements; therefore, no additional, related, costs are envisioned.

Calculation

The new formula is defined as:

$$\text{Total costs} = \left(\frac{\text{Value of R\&D}}{\text{AI unit value}} \right) \times \text{compliance cost of AI unit} + \text{conformity costs}$$

$$\text{Total costs} = \left(\frac{\text{€ 3.45 mln}}{\text{€ 170 k}} \right) \times \text{€ 29,276.80} + \text{€ 16,800} = \text{€ 611,000}$$

The total costs in Scenario 2, modelled on a representative SME, equal **about € 611,000**.

Insights

The compliance cost in this scenario would equal 2.7% of total revenues. These costs are far more feasible for an SME; however, keeping IARR estimates and considering an average hourly rate of € 32, the representative SME would still need more than 10 FTEs in total costs to ensure compliance with the requirements.

SCENARIO 3:

An alternative approach

To estimate the **total cost of compliance**, an alternative approach is proposed in this section. This scenario moves away from the pure standard cost model approach analysed thus far, and a new method to calculate total costs is discussed below. As per the previous scenario, costs are calculated for a modelled SME (see Table 7).

Approach

The new approach assumes that an AI provider incurs (i) annual fees for software platforms, (ii) annual compliance activity costs and (iii) yearly conformity assessment costs.

Regarding (i) **software platform fees**, it is assumed that a significant portion of total costs for AI providers includes annual fees for data governance, as well as AI governance platforms and Quality Management System (QMS) costs that are acquired on a Software-as-a-Service (SaaS) basis. It is acknowledged that some overlap exists across the functionalities of these software platforms. Furthermore, for the purpose of this analysis, software platform implementation costs are treated separately.

Data governance specifies a cross-functional framework for managing data as a strategic corporate asset, assuring not only that data are available, consistent, usable, trusted and secure, but also that the organisation achieves the standardisation of data definitions. Based on market analysis¹² and consultation with industry experts who validated our research, it is assumed that annual fees for data governance and data quality platform can reach up to **€25,000 per year for a SME similar to those considered in our model** (see Table 6).

AI governance platforms are crucial to ensuring that an organisation's use of AI technologies aligns with its respective strategies, objectives, and values. AI governance goes beyond simply governing data, and while data governance is necessary for effective AI governance, it is not independently sufficient.

Internal intelligence and consultation with experts suggest that annual fees for AI governance platform can reach up to **€ 50,000 per year for a SME similar to the one considered in our model** (see Table 6).

Finally, QMS systems are required to ensure quality assurance and support document control, complaints and auditing management. IARR values are maintained in this Scenario when estimating costs of QMS platform. QMS system costs are, thus, assumed to be **€ 71,400 per year**.

Based on the above, the **annual fee for software platforms is considered to reach up to € 146,400 per year**.

In Scenario 3, (ii) annual activity **compliance costs** are calculated in relation to R&D costs. Similarly to Scenario 2, R&D costs are assumed to be 15% of the total revenues and thus account for about € 3.4 million. Based on the evidence collected, it is assumed that compliance costs for a SME range on average between 2% and 6% of R&Ds. For this analysis, an average of 4% is applied to R&D to calculate **costs of compliance**. Hence, the incremental cost of compliance is estimated at about **€ 138,000**.

Finally, (iii) **conformity assessment costs** are calculated using the values presented in the IARR. These costs are expected to reach up to **€16,800**.

¹² https://www.softwaretestinghelp.com/data-governance-tools/#8_Talend. Talend can cost between \$100 and \$1000 per month, while Informatica starts at \$2000 per month.



Calculation

The formula to calculate costs for an AI developer in Scenario 3 includes cost for compliance, software development costs and conformity costs. It doesn't include one-off costs to set up the infrastructure (see table 6).

$$\text{TOTAL COST} = \text{Software development costs} + \text{Compliance costs} + \text{Conformity costs}$$

The sum of all costs described above suggests that SMEs will bear a total cost of **€ 301,200 million**.

Insights

Compliance costs for the modelled SMEs account for about 1.3% of the total revenues. Compared to Scenarios 1 and 2, this approach provides a more realistic model whereby software subscription costs are also included. Furthermore, calculations show that the additional FTEs needed to comply with the new requirements is substantially lower (2.75 FTEs). Based on the results of the analysis showed above, the likelihood of an SME taking up AI technology increases significantly, despite the associated costs incurred by the adoption of the AI Act.



OUR PROPOSED APPROACH TO ESTIMATING BENEFITS FOR SMEs

Having laid out the three main approaches to calculating the total costs for SMEs, we now turn to potential factors that may lessen the burden of complying with the proposed AI Act. It is expected that market mechanisms, such as learning curve and spill-over effects, can generate potential benefits in the medium-long term. The **learning curve** theory argues that tasks require less time and resources the more they are performed, due to proficiencies gained as the process is learned¹³. Therefore, the recurring costs of compliance that SMEs will incur in after the regulation is introduced will likely diminish once a certain degree of proficiency is achieved. At the same time, it is also likely that intersectoral knowledge **spill-over effects** will produce cost savings as more companies adhere to the regulation and specialise in compliance activities. The 2018 entry into force of the GDPR has already forced many businesses to update/review their processes in light of compliance procedures, therefore it is probable that the AI Act will be less burdensome. Additional cost savings could be achieved when synergies within the SMEs ecosystem are considered. Concrete actions included in National Recovery and Resilience Plans (NRRPs), as well as activities promoted by European Digital Innovation Hubs (EDIHs) could play a crucial role in supporting SMEs adopting measures to comply with the new AI Act. Although not operative yet additional cost savings could stem from emerging European initiatives such as the testing and experimentation facilities (TEFs). As discussed in the next section, we believe that the most meaningful savings will happen at local level through the help of European Digital Innovation Hubs (EDIHs).

ACHIEVING ECONOMIES OF SCALE: European Digital Innovation Hubs and their role

Since 2016, Digital Innovation Hubs have been working at the **forefront supporting the digital transformation and the uptake of new technologies by SMEs**. With the deployment of a new network of- 136 European Digital Innovation Hubs (EDIHs) financed via the Digital Europe Programme, plus 82 EDIHs that received the “Seal of Excellence” and the upcoming launch of a second call to further expand the network, the European Commission confirmed its commitment and support for DIHs and what has become a distinctly European approach towards digitisation and AI. Indeed, the **European economy is characterized by a significant degree of fragmentation, a high share of SMEs and uneven levels of digitization**. DIHs have already proven to be capable of supporting local SMEs. On the other hand, **the upcoming challenge for the next years will be achieving economies of scale and scope at the ecosystem level**, so to overcome the intrinsic challenges of a fragmented economy.

This aim is possible if EDIHs successfully share knowledge, standards, practices, and develop common services across Europe. The newly born network offers this opportunity, as collaboration among EDIHs is one of the cornerstones of the initiative. Another promise of the EDIH network is a specific focus on AI, as more than half (59%) of EDIHs are specialised in the provision of AI services, with at least one AI EDIH per country, ensuring geographical coverage and balance. In this context, it is evident that **EDIHs can greatly contribute to reducing SMEs costs associated to meeting the AI requirements**. The potential role of EDIHs in supporting AI certifications and conformity assessments has already been acknowledged by the European Commission¹⁴⁻¹⁵, and was briefly mentioned in the IARR. Further developing this concept, we contend that EDIHs could contribute to lowering the costs for SMEs by:

¹³ <https://hbr.org/1964/01/profit-from-the-learning-curve>



Developing and offering trainings on AI requirements and compliance: EDIHs can work as regional antennas, disseminating the latest regulatory developments and offering trainings to SMEs. Standard trainings and materials developed at the network level can be further tailored and deployed by each EDIHs according to the maturity of their local ecosystem and specific strategic sectors. This can reduce **SMEs one-off costs related to training** of the workforce, while achieving economies of scope and scale in the development of training materials.

Offering services to support SMEs in compliance activities: EDIHs specialised in AI should offer SMEs legal, technical, and management assistance for compliance activities. This could include support for activities related to recordkeeping and information provision, as well as in the development of algorithms and in the set-up of ethics-related organisational measures. This can contribute to **reducing both recurrent and one-off costs**, while also increasing trust in the market through the involvement of external specialised competence centres.

Fostering a standard - yet specialised - approach to compliance activities across Europe, thus facilitating economies of scope: as each EDIH is specialised and will acquire increasing competencies in the strategic sectors of their region, in line with the Smart Specialization Strategy (S3) of each region, there is a great opportunity for collaboration, knowledge sharing, and complementary services across Europe. Indeed, different sectors raise specific challenges to the development of AI solutions, in terms of, e.g., data used and biases or different transparency needs, and consequently to compliance activities. As an example, if standard approaches are developed at network level, an EDIH specialised in supporting the digitisation of the agrifood sector will be able to support SMEs working in this sector from other regions, whose economy focuses on different industries. The EDIH network should then be leveraged to facilitate SMEs' access to the needed competences and services when these are not offered by the local ecosystem. By collaborating and sharing knowledge, EDIHs can further reduce the costs associated to the development of compliance services, thus achieving economies of scale which will benefit SMEs. By simultaneously maintaining their specialisation, EDIHs will contribute to realising economies of scope.

By acting as the nearest point of entry to testing and experimentation facilities (TEFs) EDIHs can facilitate the uptake of trustworthy AI in Europe. From 2023, TEFs will play a key role in supporting regulatory sandboxes that can be established within the existing legislation by providing infrastructural and technological environment for testing and experimentation under the close supervision of the competent national authorities. Furthermore, TEFs may provide technical support (for example regarding fairness, transparency and robustness), as well as testing facilities to providers of AI systems who could test, in a controlled environment, whether their innovative AI-based products and services meet applicable safety requirements and standards. In line with state aid, SMEs will be able to use TEFs without paying for the support and services offered by them.

A quantification of benefits linked to EDIHs and TEFs support is not possible at this stage. However, some cost savings are identified and described in the section below.

¹⁴ EC & EIB, June 2021 "Artificial intelligence, blockchain and the future of Europe", p. 14-15. Among the recommendations to support the take-up of AI in the market, the report recommends developing a risk-based framework to assess and certify AI technologies that meet EU-wide "trustworthiness", ethical and regulatory requirements, suggesting this should be coordinated and offered by EDIHs.

¹⁵ EC COMM (2021) 205, April 2021, "Fostering a European Approach to AI", p. 37. The EC and the Member States communicated that they will analyse the feasibility of using EDIHs to assist in assessment and certification of AI technologies.

SCENARIO 3B:

Alternative approach foreseeing potential benefit from EDIHs

This last scenario is developed to model the potential benefits, in terms of cost savings, arising from the EDIHs' support discussed above. Scenario 3 is modified in the section below to include benefits foreseen from the involvement of EDIHs. In particular, the model assumes that some activities can be absorbed by the EDIHs, consequently lowering costs for individual SMEs. Specifically, EDIHs are expected to partially absorb all typologies of costs discussed above.

Approach

With regards to **compliance cost**, a way to estimate the cost savings for SMEs is to identify what portion of these costs could be absorbed by the EDIHs. The proportion of costs absorbed by EDIHs and total costs for AI providers is calculated based on the number of minutes required to conduct each activity. Based on the IARR, a total of 20,582 minutes is required to conduct all compliance activities. According to our expertise and consultation activities, we assume that EDIHs will absorb:

- 100% of document and recordkeeping costs;
- 50% of information provision costs.

The remaining requirements will be covered 100% by AI providers. Specifically:

- Training data
- Human oversight
- Robustness and accuracy

Considering that EDIHs will fully cover document and record keeping, and partially (50%) cover information provision requirements, 27% of total costs (€ 37,756) is assumed to be absorbed by the **EDIHs** and the remaining 73% **compliance costs** (€ 100,244) will be borne by the **AI provider**.

A similar approach is followed to calculate **conformity assessment costs**, on the basis of costs distribution across requirements. Assuming that EDIHs would fully absorb conformity costs for document and record keeping, and 50% for information provision, about 21% (**€ 3,500**) of total conformity costs will be covered by EDIHs. The remaining 79% (**€ 13,300**) represents the **conformity costs** borne by the **AI provider**.

In addition, assuming that EDIHs could absorb the same level (21%) of costs in terms of software platform fees, AI providers would sustain only a portion (79%) of these costs, which would reach up to **€ 115,900 per year**.

Finally, assuming that EDIHs operate without making profits, SMEs would benefit from their support in toto.



Calculation

If EDIHs are taken into account, the total cost for SMEs would decrease by almost a quarter compared to Scenario 3. Total costs for AI provider would amount to **€ 229,444**, and complying with the AI Act, as currently proposed, would have a much lower impact on SMEs (2.02 FTEs), making compliance with the AI Act more feasible for SMEs.

Insights

EDIHs can play a key role in the efficient and successful up-take of the AI Act by the market. However, this requires a clear vision and strong coordination. EDIHs are already reflecting on how to support SMEs in the up-take and development of ethical and human-centric AI solutions, through legal, technical, and management services.¹⁶ These efforts should be supported by a strategic vision, to ensure coordination among EDIHs, and to raise awareness of opportunities and challenges among all market actors.

¹⁶ Most notably, in the context of the Horizon 2020 project DIH4AI, consortium partners have defined and proposed a set of legal and ethical services to be offered by EDIHs in the field of AI, taking into account the latest regulatory developments. Some of these services are already being offered while others are being tested through open calls and experiments. For more information: <https://www.dih4ai.eu/project>



CONCLUDING REMARKS

This paper represents a **first attempt to analyse the impact the AI Act will have on SMEs**, acknowledging the fact that a better-regulated market is the only way to achieve AI that is trustworthy and fair. However, **greater attention should be given to SMEs**, which are at the forefront of innovation but can easily be crippled by high compliance costs.

The table below summarises the outcome of the analysis presented above. As discussed, using the value of R&D (Scenario 2 – R&D), as opposed to the total AI market value (Scenario 1 – IARR), provides a more accurate assessment, given the type of costs the upcoming AI Act entails. We believe that considering software platform subscription costs and calculating compliance costs based on R&D investments (Scenario 3 – Alternative) would give a more realistic estimate for SMEs. In addition, as shown in the table below, support from EDIHs (Scenario 3b – EDIH) would drastically reduce costs for SMEs. Indeed, in this manner, SMEs could benefit from several synergies that would lead to substantial cost savings, enabling them to flourish.

Table 8 • Different scenarios to calculate total costs

	Scenario 1 IARR	Scenario 2 R&D	Scenario 3 Alternative	Scenario 3b EDIH
Total costs for SMEs (€)	3,977,779	610,947	301,200	229,444
Total costs as % of revenues	17.3%	2.7%	1.3%	1.0%
FTEs	70.6	10.8	2.75	2.02

Source: Authors' computation



It can be concluded that, if the adoption costs of the AI Act are as predicted by **Scenario 1 – IARR**, the impact on SMEs **is extremely critical and could entail serious consequences**. As already explained by a policy paper published by the Center for Data Innovation ¹⁷, such a burdensome impact would not only cause profit reductions but would also push innovation and development away from the EU. Europe could also suffer from a worsening brain drain, and innovation in AI would happen in the rest of the less-regulated world.

Scenario 2 - R&D would also be particularly burdensome for SMEs, with the likely result of disincentivizing AI application development and consequently reducing uptake in the EU.

Scenarios 3 - Alternative and 3b - EDIH, on the other hand, **appear to be sustainable for SMEs and consistent with the EU goals** of increasing confidence, and thus AI up-take, and simultaneously ensuring trustworthy AI.

Our approach is based on a theoretical model which has been peer reviewed and validated by several small-to-medium AI providers. However, it is acknowledged that **further research to develop proper empirical evidence** is needed. The definition and the validation of a function model to calculate compliance cost is one of the most crucial issues. In particular, empirical research is required to validate whether a correlation between market size (revenue) and compliance costs exists. Similarly, the correlation between R&D and compliance costs has not been validated. Empirical research could strengthen the evidence for Scenario 3 - Alternative and Scenario 3b - EDIH, by further exploring the development lifecycle and the extent of compliance activities in each phase. In addition, the correlation between compliance activities and total development costs could be further assessed. Finally, **the role of EDIHs could be explored to understand the breadth and depth of concrete support they can provide to AI SMEs in complying with the new regulation**.

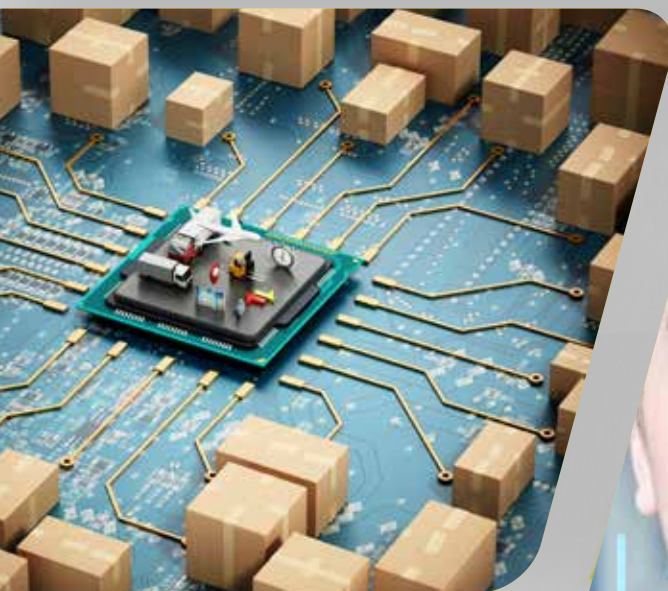
To this extent, empirical validation could be collected by assembling a panel of SMEs representative of the various Member States for both providers and users. With those SMEs, researchers would conduct a structured assessment of their AI applications involving AI application mapping, categorisation and risk-tiering. This would enable a clear “snapshot” of the costs SMEs incur in to comply with the regulation.

¹⁷ 2021-ai-a-costs.pdf (datainnovation.org)

KEY TAKEAWAYS

- *A better-regulated market is the only way to achieve AI that is trustworthy and fair*
- *Regulation should pay particular attention to SMEs*
- *SMEs are at the forefront of innovation, but can easily be crippled by high compliance costs in the short term*
- *Cost savings for SMEs can be achieved through existing (e.g. EDIHs) and emerging (e.g. TEFs) European initiatives*
- *Our approach to calculate costs for a modelled SME (scenario 3) suggests that total costs of AI Act can reach up to € 300,000, representing 1.3% of the total revenues.*
- *When EDIHs are taking into account (Scenario 3b), costs for a single SME can drop by almost 25%*
- *Further research is required to empirically validate the model proposed in this paper to calculate costs for SME provider*







THE AI ACT: HELP OR HINDRANCE FOR SMEs?

An analysis of the cost of compliance with
the AI Act for SMEs

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