



bitkom



Bundesministerium  
für Wirtschaft  
und Klimaschutz

Unter der Schirmherrschaft des

# AI Act Implementation Day

13. February 2025 - Munich



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## Disclaimer

A prerequisite for participation is **compliance with antitrust law:**  
Section 1 of the German Act Against Restraints of Competition (GWB):  
"Agreements between undertakings, decisions by associations of undertakings, and concerted practices that have as their object or effect the prevention, restriction, or distortion of competition are prohibited."

# Program

- 08:30 am**     **Arrival & Registration**
- 09:15 am**     **Welcome & Opening**  
Susanne Dehmel - Bitkom  
Dr. Frauke Goll - appliedAI Institute for Europe  
Rebekka Weiß - Microsoft Deutschland
- 09:30 am**     **Opening Keynote**  
Dr. Christoph Peylo - Robert Bosch GmbH
- 09:45 am**     **Talk: Update on AI Act implementation streams**  
Sabrina Küspert - AI Office  
Evelyn Graß - German Federal Ministry for Economic Affairs and Climate  
Amelie Buss - DIN
- 10:45 am**     **Coffee Break**



# Program

**11:00 am**    **Talk: Insights into Prohibited Practices**

Gabriele Mazzini - MIT Media Lab

**11:30 am**    **Panel: High-Risk Conformity Assessment**

Maria Frantzi - European Central Bank

Dr. Christoph Poetsch - TÜV AI.Lab

Dr. Wolfgang Hildesheim - IBM

**12:30 pm**    **Lunch Break**

**01:30 pm**    **Panel: AI Value Chain & Responsibilities**

Sebastian Dürdoth - Microsoft Deutschland GmbH

Dr. Mathis Börner - SAP SE

Prof. Boris Bauke - TH Aschaffenburg

**02:30 pm**    **Panel: Integration of AI Act Requirements in sectoral regulation**

Prof. Dr. Sonja Zillner - Siemens AG

Araceli Alcalá - Carl Zeiss

Dr. Florian Jell - Allianz

# Program

- 03:30 pm **Coffee Break**
- 03:45 pm **Talk: GPAI Model Fine-tuning**  
Maximilian Kufner - BMW
- 04:05 pm **Talk: Transparency Obligations**  
Tobias Kellner - Google Germany
- 04:25 pm **Talk: AI Literacy**  
Paula Cippiere - Ada Learning
- 04:45 pm **Closing Remarks**  
Susanne Dehmel - Bitkom  
Dr Till Klein - appliedAI Institute for Europe
- 05:00 pm **Networking & Drinks (until 7pm)**

So many questions,  
So little time!



Share your questions  
For networking and follow up activities.

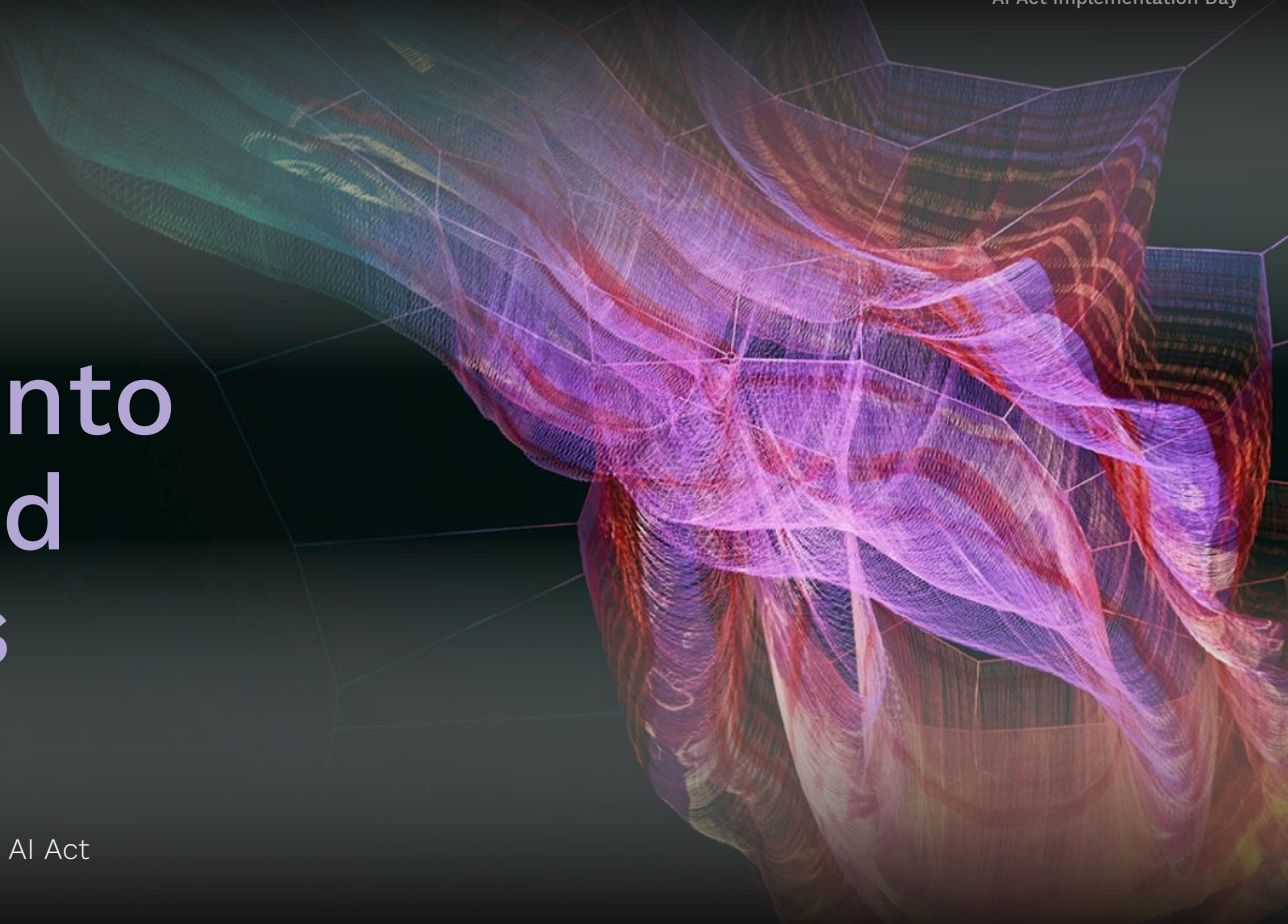
menti.com  
ID: 6332 3733

11:00 - 11:30 am

# Insights into Prohibited Practices

**Gabriele Mazzini**

MIT Media Lab, Lead author of the AI Act





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# Prohibited AI Practices of the AI Act: origin and evolution

**Gabriele Mazzini**

**Architect & Lead Author AI Act**

**MIT Media Lab Research Affiliate & MIT Connection Science Fellow**

AI Act Implementation Day by bitkom & appliedAI

February 13, 2025

Munich



EUROPEAN UNION · ARTIFICIAL INTELLIGENCE

## EU announces €200-billion AI investment push

The European Commission president told the AI Action Summit in Paris on Tuesday that the EU would contribute €50 billion with the rest pledged by 'providers, investors and industry.'

Le Monde with AFP  
Published yesterday at 1:33 pm (Paris), updated yesterday at 2:26 pm · 1 min read



MARKETS BUSINESS INVESTING TECH POLITICS VIDEO INVESTING CLUB PRO LIVESTREAM

TECH

### France unveils 109-billion-euro AI investment as Europe looks to keep up with U.S.

PUBLISHED MON, FEB 10 2025-5:19 AM EST

**Ryan Browne**  
@RYAN\_BROWNE\_

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 Prefer to listen? [Read More](#)  
 NOW UP NEXT [Share Tone](#)

KEY POINTS

- French President Emmanuel Macron on Sunday announced plans for 109 billion euros of private AI investment.
- He described the multibillion-euro commitment as France's equivalent to Singapore, referring to U.S. President Donald Trump's \$500 billion AI investment project.
- Macron announced the mammoth investment sum ahead of France's AI Action Summit, where world leaders and tech bosses are gathering in Paris this week.

TRENDING NOW

- Musk says DOGE is 'what democracy is all about' during Oval Office visit
- Trump FBI pick, Kash Patel, discussed at directing staff purge while still a nominee
- Texas drops 6% after 870 partners with DeepSeek. Musk adds to DOGE disconnections with OpenAI bid



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America's Newspaper

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LISTEN NOW **Threat Status podcast: Is the DOGE a threat to national security?**

Threat Status: High stakes of Int'l democracy  
Daniel Twining joins Guy Taylor

Listen: Higher Ground podcast  
Selena Gomez's wedding, DEI's combustion & America's education crisis

WATCH: President Trump is reshaping America's foreign policy  
With Tim Constantine and David Bozell

TRENDING: DONALD TRUMP | CHINA | JAPAN | NFL | ELON MUSK | ISRAEL | NIPPON | SUPER BOWL | UKRAINE | U.S. STEEL

HOME | NEWS | POLITICS

## Trump announces \$500 billion AI investment for new data centers, jobs



ump, from left, speaks as Masayoshi Son, SoftBank Group CEO, Larry Green, Oracle Corporation and chief technology officer, and Sam Altman, OpenAI sevellet Room at the White House, Tuesday, Jan. 21, 2025. ... more >

MARKETS BUSINESS INVESTING TECH POLITICS VIDEO INVESTING CLUB PRO LIVESTREAM

TECH

## China's DeepSeek AI dethrones ChatGPT on App Store: Here's what you should know

PUBLISHED MON, JAN 27 2025-10:13 AM EST | UPDATED MON, JAN 27 2025-4:05 PM EST

**Hayden Field**  
@HAYDENFIELD

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KEY POINTS

- The buzz around Chinese AI startup DeepSeek began picking up steam earlier this month, when the startup released R1, its reasoning model that rivals OpenAI's GPT-4o.
- On Monday, DeepSeek took over rival OpenAI's coveted spot for most-downloaded free app in the U.S. on Apple's App Store, dethroning ChatGPT for DeepSeek's own AI Assistant.
- Global tech stocks sold off, with AI chip giant Nvidia falling 10%.

TRENDING NOW

- Judge declines to block Elon Musk's DOGE from Labor Department systems
- The IRS has issued 3.2 million tax refunds this year. Here's the average payment
- RK 2: had up to \$1.2 million in credit card debt — what experts say on tackling high balances
- Trump says he's firing Kennedy Center board of trustees members and naming himself chairman
- IBM is the best Dow stock over the past 3 months, but one CIO says its AI message is disappointing



Daria Beric / Reuters

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# Introduction

# Origins

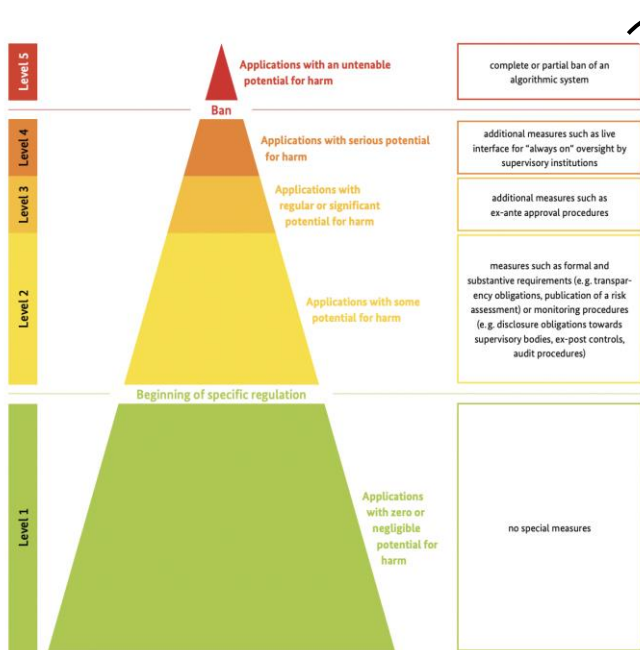


Figure 8:  
Criticality pyramid and risk-adapted regulatory system for the use of algorithmic systems

**LAW** - algorithm-determined killings



## Critical concerns

- Identifying and tracking individuals with AI
- Covert AI systems
- AI enabled citizens scoring
- LAW
- Potential long term concerns

Opinion of the Data Ethics Commission, December 2019, p. 177

HLEG ethics guidelines for trustworthy AI, April 2019, p. 33



# Context and thinking behind initial draft

- Fits well into risk-based approach
- Most restrictive & impactful legal approach - need to be very specific & 'surgical' – thread carefully!
- Safety net for 'extreme undesired behavior' that has no societal value, exceptional situations
- 'AI practices' rather than 'AI systems' – Unfair Commercial Practices Directive
- In practice likely already prohibited under EU and/or national law

# Prohibited AI Practices

**Subliminal techniques & manipulative/deceptive techniques**  
resulting in significant harm

**Exploitation of vulnerabilities**  
resulting in significant harm

**'Social scoring'** by public & private authorities

**'Real-time' remote biometric identification for law enforcement purposes in publicly accessible spaces**  
(with exceptions)

**Biometric categorisation**  
(race, political opinions, trade union membership, religion/philosophical beliefs, sex life, sexual orientation)

**Individual criminal risk assessment**

**Emotion recognition in workplace and education**  
except medical or safety reasons

**Untargeted scraping**  
of internet or CCTV for facial images to build-up or expand databases

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# Initial Prohibited AI practices

# Harmful subliminal manipulation – Art. 5(1)(a)

## *Commission AI Act proposal*

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to materially distort a~~ person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

## *Final AI Act*

(a) the placing on the market, **the** putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness **or purposefully manipulative or deceptive techniques, with the objective, or the effect** of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person **or group of persons significant harm;**



# Harmful exploitation of vulnerabilities - Art.5(1)(b)

## *Commission AI Act proposal*

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, ~~in order to materially distort~~ the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

## *Final AI Act*

(b) the placing on the market, the putting into service or the use of an AI system that exploits any of the vulnerabilities **of a natural person** or a specific group of persons due to their age, disability **or a specific social or economic situation, with the objective, or the effect, of** materially **distorting** the behaviour of that person **or a person belonging to that group** in a manner that causes or is **reasonably** likely to cause that person or another person **significant harm**;

# 'Social scoring' – art. 5(1)(c)

## *Commission AI Act proposal*

the placing on the market, putting into service or use of AI systems ~~by public authorities or on their behalf~~ for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:

- (i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;
- (ii) detrimental or unfavourable treatment of certain natural persons or groups of persons that is unjustified or disproportionate to their social behaviour or its gravity;

## *Final AI Act*

the placing on the market, the putting into service or the use of AI systems for the evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, **inferred** or predicted personal or personality characteristics, with the social score leading to either or both of the following:

- (i) detrimental or unfavourable treatment of certain natural persons or groups **of persons** in social contexts **that** are unrelated to the contexts in which the data was originally generated or collected;
- (ii) detrimental or unfavourable treatment of certain natural persons or groups **of persons** that is unjustified or disproportionate to their social behaviour or its gravity;

# Real-time remote biometric identification - Art. 5(1)(h)

## *Prohibition with three exceptions*

- **Searching for victims** of abduction, trafficking, or sexual exploitation, and locating **missing persons**
- Preventing a specific, serious, and immediate **threat to the life or physical safety** of individuals, or addressing a real and imminent or likely **terrorist threat**
- Locating or identifying a **person suspected of committing a criminal offense**, in order to carry out a criminal investigation, prosecution, or enforce a criminal penalty for certain offenses (listed in Annex II) that are **punishable in the Member State** by a custodial sentence or detention order for at least four years

## *Procedural requirements*

- **National law** authorising the use
  - establish **safeguards and conditions** in relation to the use, in particular as regards the temporal, geographic and personal limitations, **specifically state objectives** and **criminal offences** (Annex II) for which use is authorized
  - MS may introduce **more restrictive laws** on use
- **prior authorisation** for each use by judicial authority or independent administrative authority
- **prior FRIA & registration of system** in EU database
- **each use notified** to DPA and MSA
- **DPA and MSA to submit annual reports** to COM on use, incl. # of authorisations & **COM to publish annual reports**

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# New Prohibitions



# Criminal risk assessment - Art. 5(1)(d)

The placing on the market, the putting into service for this specific purpose, or the use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person committing a criminal offence, **based solely on the profiling of a natural person or on assessing their personality traits and characteristics**; this prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity

## Untargeted scraping to develop facial recognition databases - Art. 5(1)(e)

The placing on the market, the putting into service for this specific purpose, or the use of **AI systems that create or expand facial recognition databases** through the **untargeted scraping of facial images from the internet or CCTV footage**

## Emotion Recognition - Art. 5 (1) (f)

The placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person **in the areas of workplace and education institutions**, except where the use of the AI system is intended to be put in place or into the market for **medical or safety reasons**

## Biometric Categorization - Art. 5(1)(g)

The placing on the market, the putting into service for this specific purpose, or the use of biometric categorisation systems that categorise individually natural persons based on their biometric data to **deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation**; this prohibition does not cover any labelling or filtering of lawfully acquired biometric datasets, such as images, based on biometric data or categorizing of biometric data in the area of law enforcement

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# Thank you!

[gmazzini@llm10.law.harvard.edu](mailto:gmazzini@llm10.law.harvard.edu)

[mazzini@mit.edu](mailto:mazzini@mit.edu)

11:30 am - 12:30 pm

# Panel 1: Conformity Assessment in Action: Processes, Products & People

11:30 am - 12:30 pm

## Panel: High-Risk Conformity Assessment

Provider

Article 6

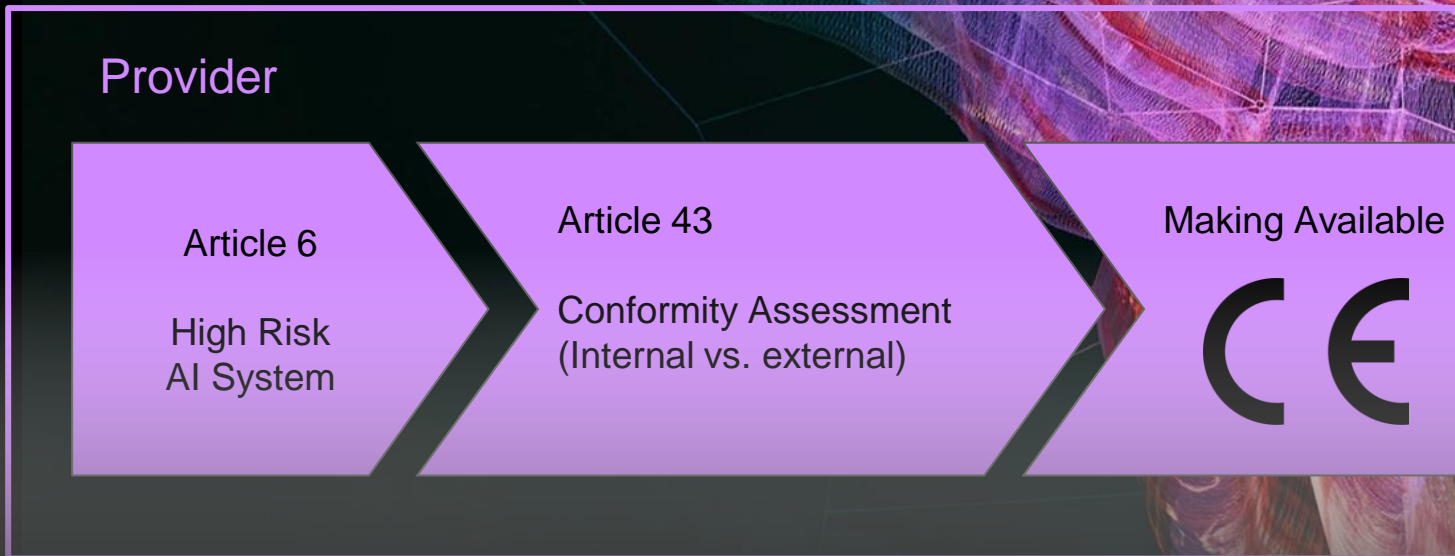
High Risk  
AI System

Article 43

Conformity Assessment  
(Internal vs. external)

Making Available

CE





11:30 am - 12:30 pm

# Conformity Assessment in Action: Processes, Products & People

**Dr. Christoph Poetsch**

Head of AI Quality and Ethics, TÜV AI.LAB





# Pillars to effectively implement the AI Act

Dr. Christoph Poetsch

Head of AI Quality and Ethics @ TÜV AI.Lab

## Keep calm & carry on, but ...

Instead of “all regulation off”, we should stick to Europe’s USP “safety & innovation” — but: Europe needs to do its homework, we have to regulate better & more efficiently

## Standards and Guidelines

Standards and guidelines need to be timely and concrete enough to plan, to develop and to test, that means w.r.t. all relevant do-mains and AI technologies

## Efficient implementation

Concise structures w.r.t. relevant public authorities, equal implementation across Europe (no “gold-plating” ), and efficient certification pipelines

## Innovative Potentials

Assessments and high standards as advantage on the market — but: comprehensive and strict enforcement to have a level playing field for all stakeholders

11:30 am - 12:30 pm

# Conformity Assessment in Action: Processes, Products & People

**Dr. Wolfgang Hildesheim**

Head of Watson, Data Science & AI, IBM Deutschland

# EU AI Act – 1-pager for Executives ?!?

1. Which AI systems do we have?

2. Do we have a homogeneous **risk assessment “a la EU AI Act”**?

3. Which AI systems are **“high risk”** ? (5-15% of systems)

- Option 1: Conformity assessment by third party, f.i. TÜV, Phönix Labs...
- Option 2. Self-conformity using the 8-10 European harmonized AI-standards

4. Which AI systems are **“not high risk”** ? (85-95% of systems)

- No conformity tests needed
- Transparency need related to the GPAI-models
- System tests needed in the “usual sectors”, f.i. automotive, medical, telco...

# AI - What keeps a company Executive awake at night ?

Do I have a good AI strategy?

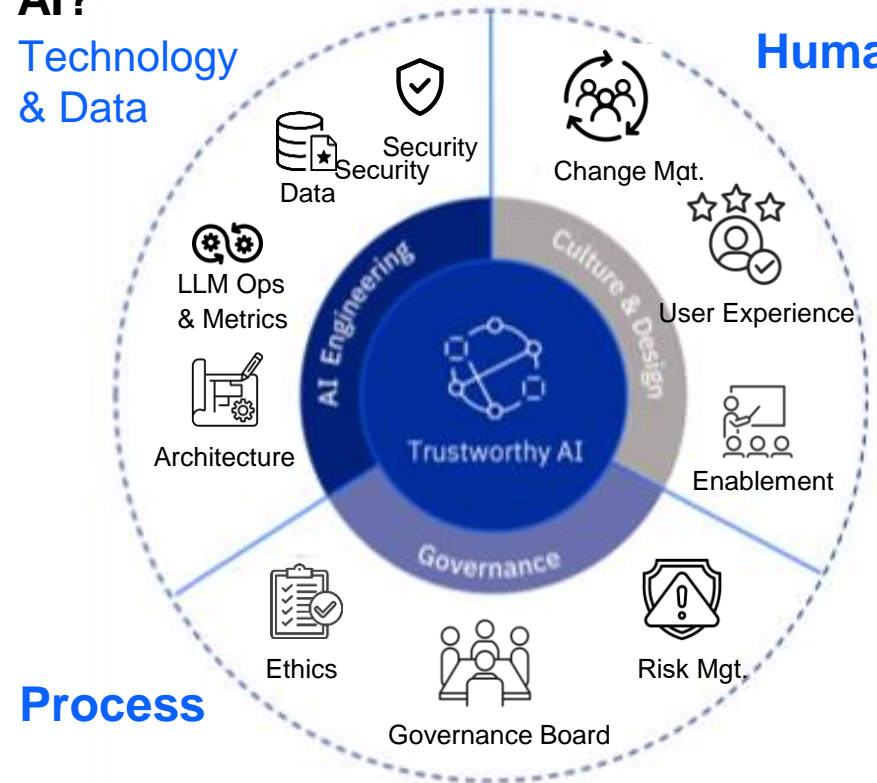
Are the 6 success factors of AI covered?

1. **AI People** = Talent with AI expertise
2. **AI Data** = Collections- & Data-Management
3. **AI SW** = Access & Knowledge about AI SW
4. **AI Innovation Culture** = „use case focus“, „step-by-step“ & „fail fast“ approach
5. **AI eco-system** = business-& tech-partners
6. **AI governance** = Trustworthiness & Compliance with EU AI Act

Do I have the elements of a Trustworthy AI?

Technology  
& Data

Human

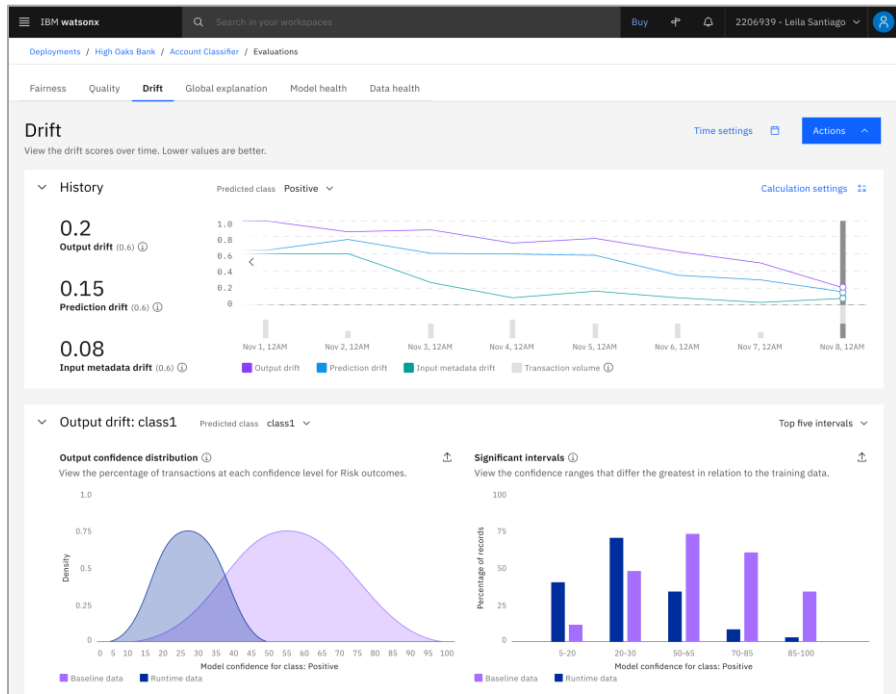


Process

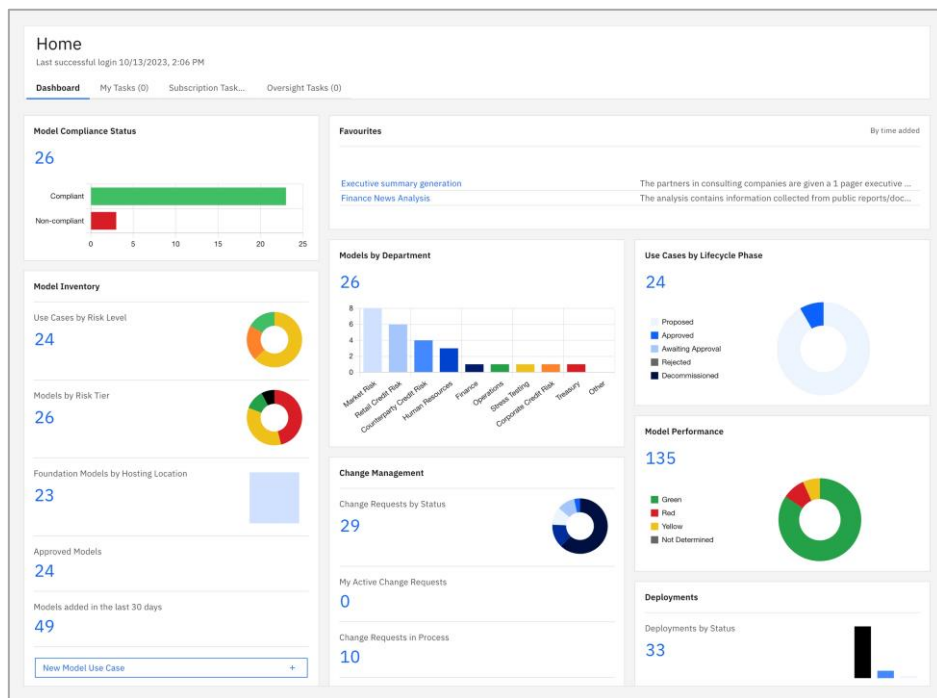
# Watsonx.governance ↻

Monitor the performance of your models and AI governance via dashboards

## Evaluation and Monitoring



## Risk Management and “best practices”



# Example



# AI Recognition of buildings and outlines

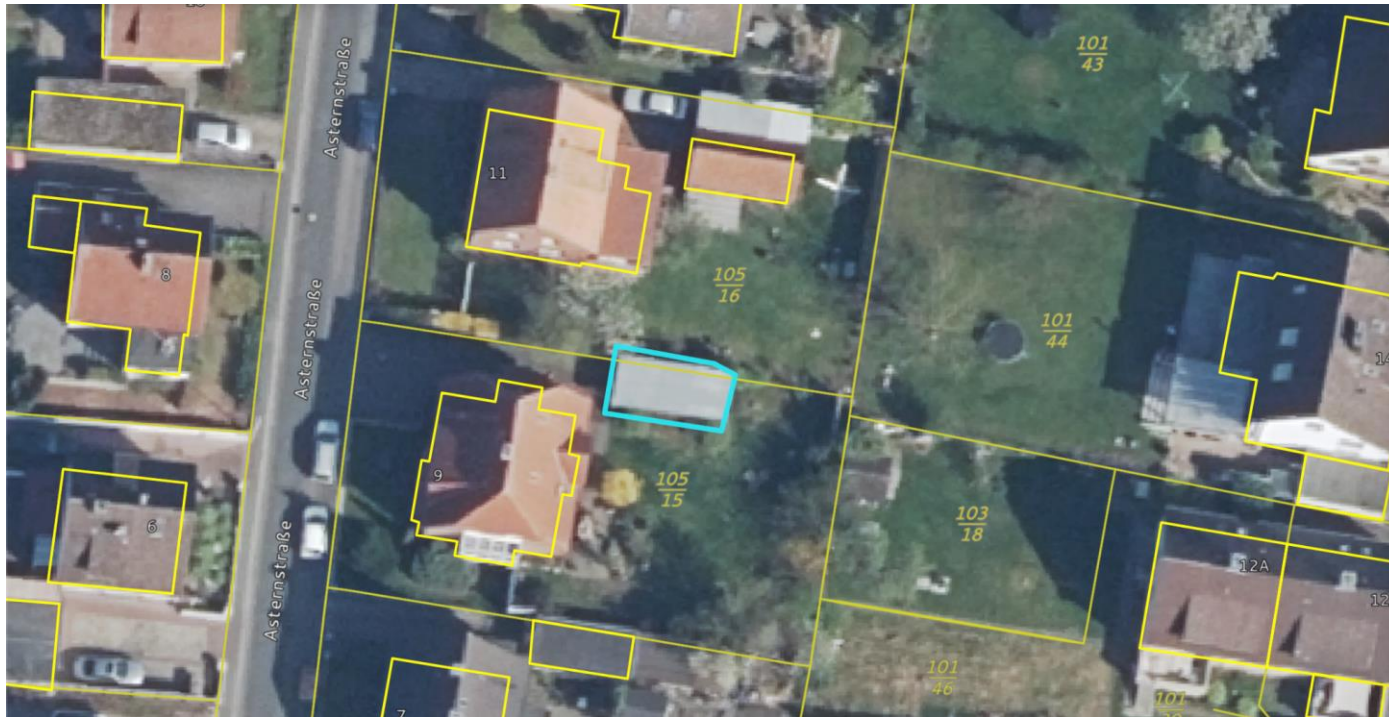


Figure 11.1: Use case for AI: Find the few missing buildings (here a garage in blue) in the buildings (here garage in blue) in the mass data of the real estate cadastre (buildings and parcels in yellow)

<https://www.amazon.de/K%C3%BCnstliche-Intelligenz-managen-verstehen-book/dp/341031458X>.


v0.18.3

Cloud-Services

## Cloud-Services

### Filter

Anbieter (1) 

Portfoliokategorie 

Serviceart 

Servicekategorie 

Alle zurücksetzen

Landesamt für Geoinformat... 

Suchbegriff eingeben ... 

Name A-Z 

### KI-Gebäudeerkennung

Mit der KI-Gebäudeerkennung können Nutzende Gebäude in Luftbilddaten automatisch erfassen lassen, um damit z.B. den Gebäudebestand eines Liegenschaftskatasters zu aktualisieren.

[Mehr](#)

SaaS



# AI Trustworthiness Label to support the GTM

<https://www.amazon.de/K%C3%BCnstliche-Intelligenz-managen-verstehen-book/dp/341031458X>

<h2>Artificial Intelligence</h2> <p>The AI model recognises objects on satellite images. The model is trained on building locations, building outlines, building types and other building properties. The satellite images are composed of different sensor data: optical images, lidar images.</p>	<b>Manufacturer: LGLN</b> <b>Model version: V2.3 aus 2022</b>		<b>Risk very low</b>
	<b>Application: Object recognition on aerial photographs</b>		
	<b>Capability</b>	<b>Method</b>	<b>Data</b>
	<b>Percept</b> >External >>See	Machine Learning >Supervised Learning >>Neural Network	Training input: known quality-checked satellite images (optical, infrared) and lidar data Operational data: unknown images
	<b>Process</b> >Facts >>Select >>Verify	Machine Learning >Supervised Learning >>Neural Network	Building location ,+-xx cm, Building outline ,+- yy cm
	<b>Act</b>		
	<b>Communicate</b>		



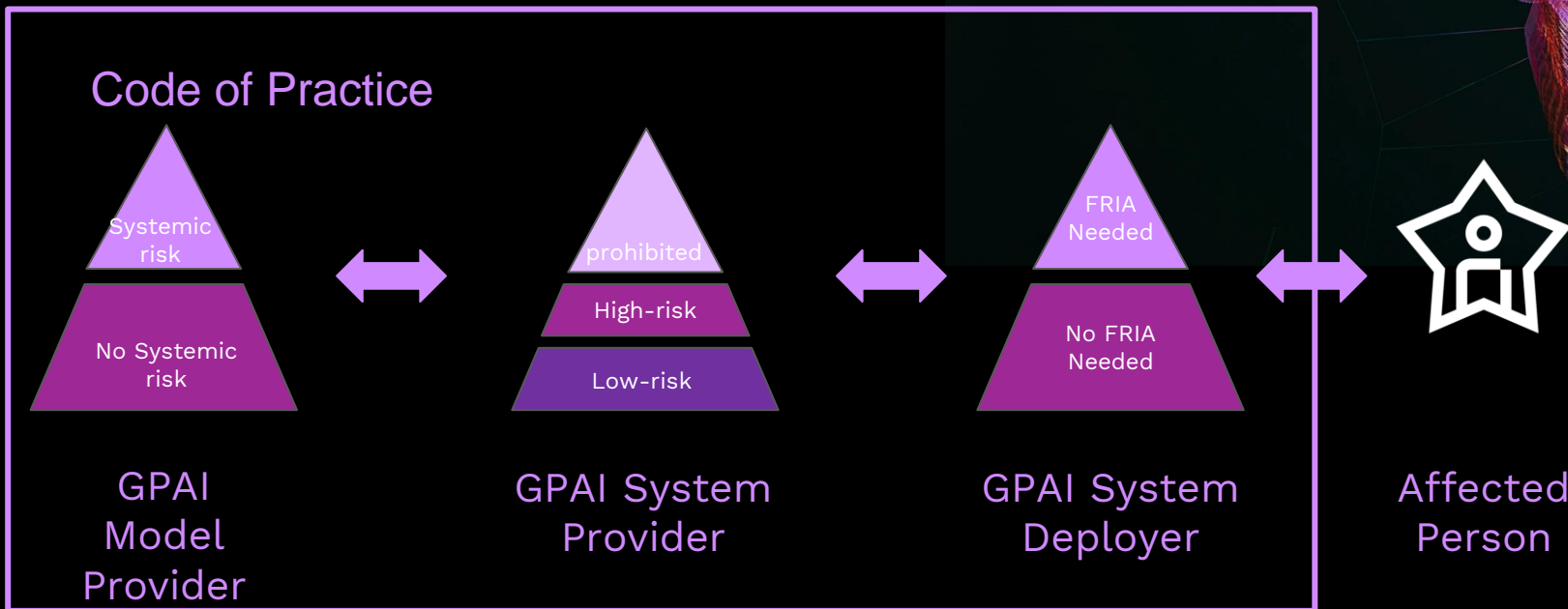
01:30 - 02:30 pm

# Panel 2: AI Value Chain & Responsibilities



01:30 - 02:30 pm

## Panel 2: AI Value Chain & Responsibilities



01:30 - 02:30 pm

# AI Value Chain & Responsibilities

**Sebastian Dürdoth,**  
Senior Corporate Counsel, Microsoft Deutschland

# Pillars to effectively implement the AI Act

Dr. Christoph Poetsch

Head of AI Quality and Ethics @ TÜV AI.Lab

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## Efficient implementation

Concise structures w.r.t. relevant public authorities, equal implementation across Europe (no “gold-plating” ), and efficient certification pipelines

## Innovative Potentials

Assessments and high standards as advantage on the market — but: comprehensive and strict enforcement to have a level playing field for all





# The AI value chain

Supporting customers on  
their AI compliance journey

Sebastian Dürdoth  
Senior Corporate Counsel



CELA  
Customer &  
Partner Solutions



# Just like cloud, AI is a shared responsibility

IaaS  
(BYO Model)

PaaS  
(Azure AI)

SaaS  
(Copilot)

		IaaS (BYO Model)	PaaS (Azure AI)	SaaS (Copilot)
<b>AI Usage</b> <i>(AI - Process)</i>	User Training and Accountability	Customer	Customer	Customer
	Usage Policy, Admin Controls	Customer	Customer	Customer
	Identity, Device, and Access Management	Customer	Customer	Shared
	Data Governance	Customer	Customer	Shared
<b>AI Application</b>	AI Plugins and Data Connections	Customer	Customer	Shared
	Application Design and Implementation	Customer	Customer	Shared
	Application Infrastructure	Customer	Shared	Shared
	Application Safety Systems	Customer	Shared	Shared
<b>AI Platform</b>	Model Safety & Security Systems	Customer	Shared	Shared
	Model Accountability	Customer	Shared	Shared
	Model Tuning	Customer	Shared	Shared
	Model Design & Implementation	Customer	Shared	Shared
	Model Training Data Governance	Customer	Shared	Shared
	AI Compute Infrastructure	Shared	Shared	Shared

Microsoft

Model Dependent

Shared

Customer

# How Microsoft supports customers on their AI compliance journey



Mitigate AI risks



Provide transparency



Share RAI learnings



Support AI skilling

<http://aka.ms/rai>

<https://aka.ms/EUAIAct>  
(AI Literacy Starting Guide)



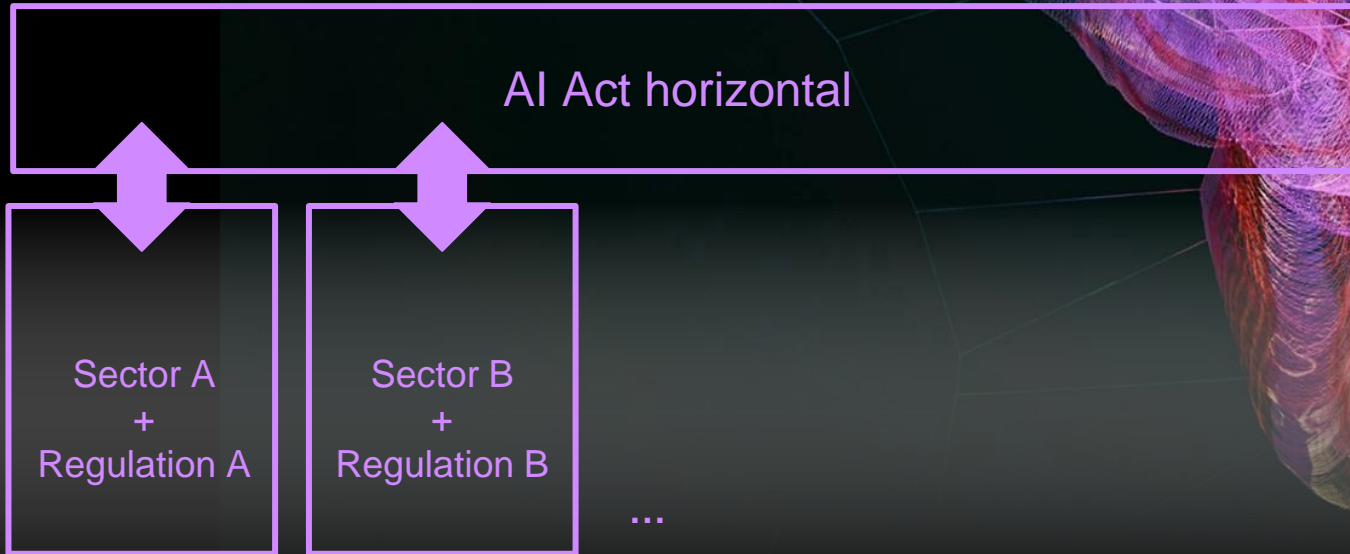
02:30 - 03:30 pm

# Panel 3: High Risk & Sectoral Regulation



02:30 - 03:30 pm

# Panel 3: High Risk & Sectoral Regulation



# How Siemens is getting prepared for the upcoming AI regulations, such as the AI Act?

13<sup>th</sup> February 2025

AI Act Implementation Day

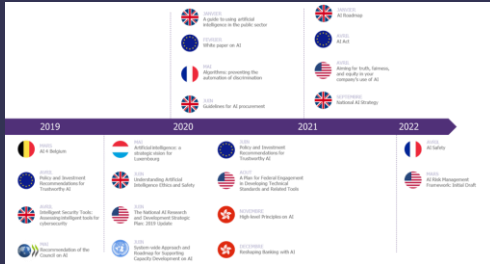
Prof. Dr. Sonja Zillner



**SIEMENS**

# Emerging regulatory landscape for Data & AI .....

.....requires a consistent and comprehensive framework across the organization



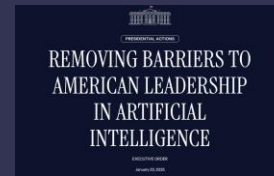
On international level.....

<p><b>European Chips Act</b> Strengthening Europe's competitiveness and resilience in semiconductor technologies.</p>	<p><b>European Digital Identity</b> Giving you full control on how much information you share with third parties.</p>
<p><b>Artificial Intelligence</b> Achieving better healthcare, safer and cleaner transport, more efficient manufacturing, and cheaper and more sustainable energy through AI.</p>	<p><b>European data strategy</b> Making the EU a role model for a society empowered by data.</p>
<p><b>European industrial strategy</b> Ensuring European industry leads the transition towards climate neutrality and digital leadership.</p>	<p><b>Contributing to European Defence</b> Working together to tackle security threats and challenges more robustly.</p>

...covering various digital and data related aspects



Risk based approach of the EU AI ACT



Removing Barriers to American Leadership in AI- Trumps Executive Order



China Global AI Governance released AI governance regulation



Guiding principles & codes of conduct for AI (G7 Hiroshima AI process)

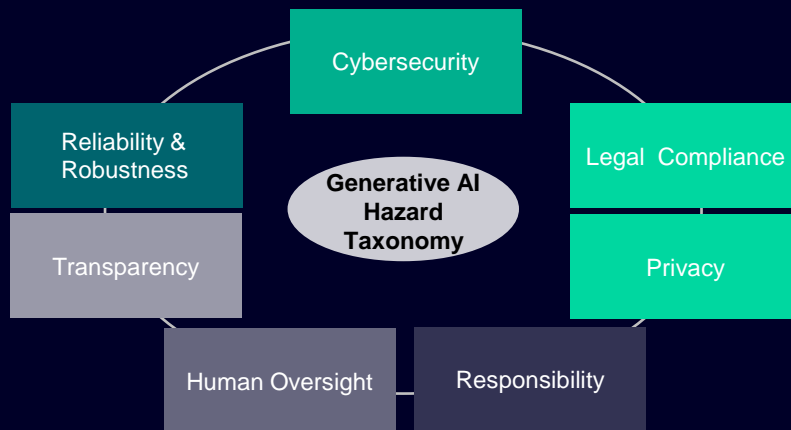


# The Siemens Generative AI Governance approach is risk-based

## Siemens Generative AI Risk Management Framework

### Generative AI Risk & Hazard Methodology....

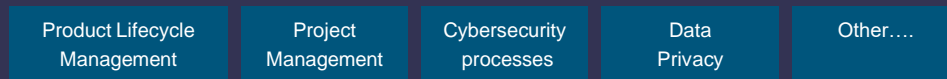
- **Risk Profiling and Classification** to determine the criticality of Generative AI applications
- **Generative AI Risk/Hazard Taxonomy** to guide the risk identification
- **Mitigation Guideline** to assess and mitigate Generative AI triggered risks
- **Process Description** defining roles, responsibilities, milestones, quality gates and decision points
- **Best Practices of Pre-approved architectural Patterns** to speed up the evaluation process



...enabling the **systematic** identification of **risk sources** while developing & deploying GenAI applications

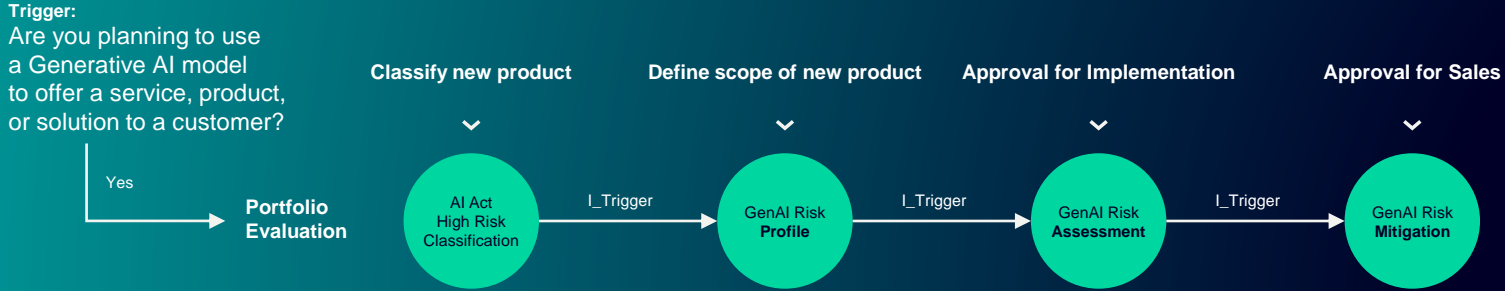
### ....is mapped to the related organisational processes

by defining roles, responsibilities, milestones, quality gates & decision points



# Generative AI Risk Management Framework

## Embedding into the Product Lifecycle Management Process



“Are you high-risk in accordance to the AI Act?”

“Describe the intended purpose of the GenAI and the data flow?”

“Check Generative AI risk list & define risk mitigation measures”

“Implement the defined mitigation measures e.g., robust AI, explainable AI”

Supported by **Generative AI Risk Methodology**

**AI Risk Classification Methodology** to determine the criticality of the AI Product

**Intended purpose description** to define the scope of the GenAI risk assessment

**Generative AI Risk List** to guide the risk identification and scope mitigations

**Mitigation Guideline** to assess and mitigate Generative AI triggered risks



# Generative AI Risk Management Framework

## Embedding into the Product Lifecycle Management Process

Trigger:  
Are you planning to use a Generative AI model to offer a service, product, or solution to a customer?

Yes

Portfolio Evaluation

Classify new product



↳ Trigger

Define scope of new product



↳ Trigger

Approval for Implementation



↳ Trigger

Approval for Sales



“Are you high-risk in accordance to the AI Act?”



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“Check Generative AI risk list & define risk mitigation measures”

“Implement the defined mitigation measures e.g., robust AI, explainable AI”

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**AI Risk Classification Methodology** to determine the criticality of the AI Product

**Intended purpose description** to define the scope of the GenAI risk assessment

**Generative AI Risk List** to guide the risk identification and scope mitigations

**Mitigation Guideline** to assess and mitigate Generative AI triggered risks

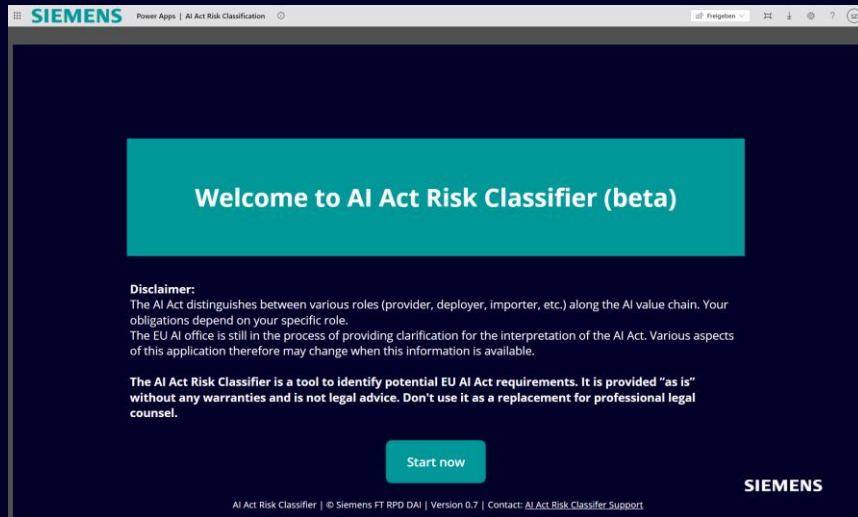




# EU AI Act Risk Classification (Compliance to AI Act)



The **AI Act Risk Classification** helps to determine the risk class/category of your AI system in accordance with the AI Act.



## EU AI Act Risk Classification

AI Act Risk classification to determine the criticality of the GenAI product.

In case of

- **Low risk:** Continue the product development
- **Transparency obligations:** Additional transparency obligations (Article §50) need to be fulfilled
- **High risk:** request expert consultancy to ensure presumption of AI Act conformity while product development
- **Unacceptable risk:** stop product development

# EU AI Act Risk Classification (Compliance to AI Act)

## Example RAG-based Q&A System



The classification services is a self-service enabling the access to legal, standardization and AI experts in case of questions



Product Manager, Team Architect



Individually or in a short session



< 30 min



Transcript is stored in the respective product development repository

**AI Act Risk Classification Transcript**

**Disclaimer**  
The AI Act Risk Classifier is a tool to identify potential EU AI Act requirements. It is provided "as is" without any warranties and is not legal advice. Don't use it as a replacement for professional legal counsel.  
The classification result is determined based on your answers to the questions posed in the AI Act Risk Classifier App. Therefore, the correctness of your answers impacts the correctness of the classification result. If you are unsure about the correctness of your answers, please contact the AI Act Risk Classification team at aiarc.t@siemens.com.

**Classification Result**

- Prohibited AI system
- High-risk AI system
- AI system with specific transparency requirements**
- Low-risk AI system
- Out of scope / no AI system

**Result:**  
AI system with specific transparency requirements

**Explanation:**  
Due to your answers to question(s) 5 a, b your AI System has additional transparency obligations according to AI Act Art. 50

**Implication for PLM Process:**

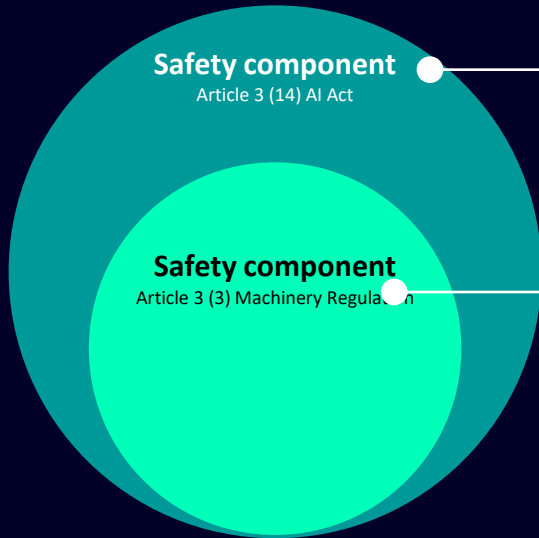
SIEMENS

FT WFO-DAI | 2025-02-06

Revised | © Siemens, 2025 Page 2

# Interplay AI Act x Machinery Regulation\*: Safety Components

The definition of safety components under the AI Act is **much broader** than in the Machinery Regulation



## AI Act

- ...fulfils a **safety function**....
- OR**
- ...failure / malfunctioning endangers the health or safety or **property**....
  - not necessary to be placed on the market separately

## Machinery Regulation

- designed or intended to fulfil a **safety function**
- AND**
- placed on the market **separately**
  - additional safety device, **no impact** on machine function
  - Machine is fully operational without the safety component



The **same component** that falls under both the AI Act and the Machinery Regulation may now be **classified differently depending on the regulatory context**.



# Implementation of the AI Act

## Our Learnings & Upcoming Challenges in a nutshell

---



Embedding AI Governance into existing organizational process is beneficial



People require explanations and/or guidance from experts



Inconsistency of legal definitions needs to be addressed!!



Harmonized AI Standards are still missing

02:30 - 03:30 pm

# High Risk & Sectoral Regulation

**Araceli Alcalá Espinosa**

Regulatory Affairs Manager, Carl Zeiss Medical



# Guiding EU AI Act Adoption with MDR Insights

Araceli Alcalá



February 13th,  
2025





Carl Zeiss Meditec AG



# Medical Device Regulation

## Our North Star for navigating the AI Act



Are companies compliant with EU legislative frameworks, like MDR, better prepared for the AI Act?



Source: Botond Horvath / Shutterstock.com

# A comparative overview of shared principles



## MDR (EU) 2017/745

## AI ACT (EU) 2024/1689

Comprehensive regulatory framework for medical devices

Comprehensive regulatory framework for artificial intelligence

Applies to all medical devices, including software

Applicable requirements commensurate to the risk AI systems can pose

Primary goal: Protect patients and users

Primary goal: Foster trustworthy AI and ethical considerations

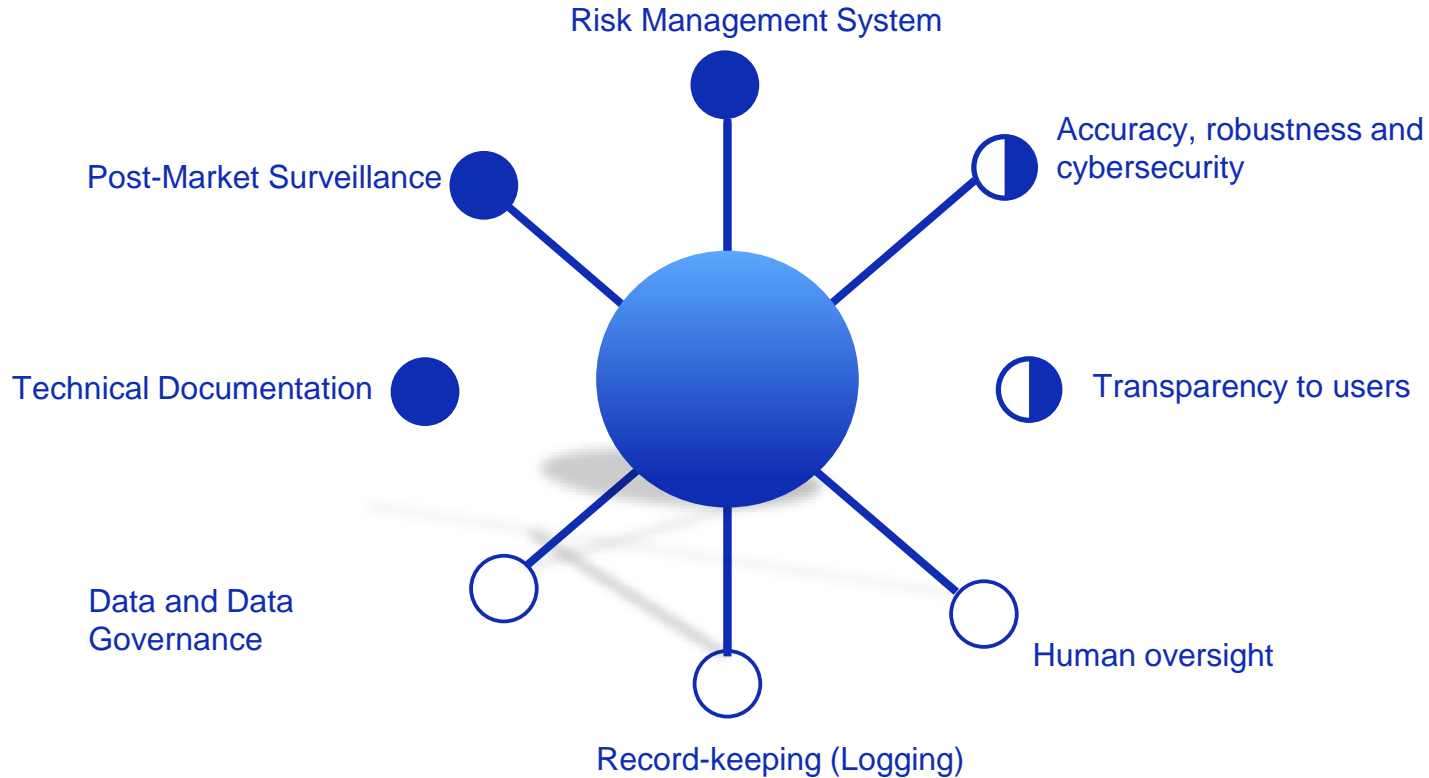
Ensures high safety standards during total product lifecycle

Ensures high safety standards during total product lifecycle

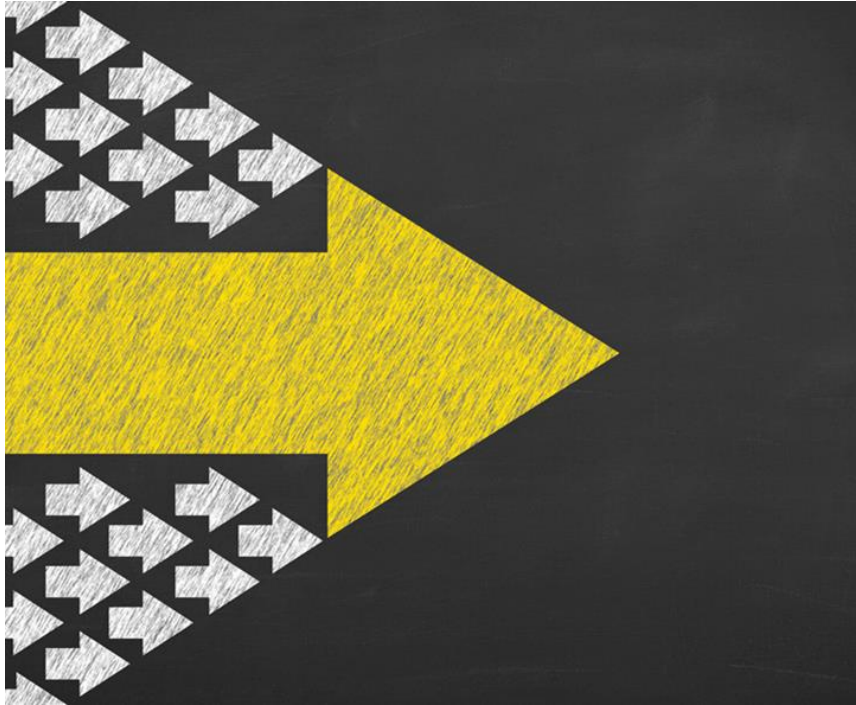
**MDR provides a strong foundation for navigating the complexities of the AI Act**

# MDR and EU AI Act

## Partial alignment of provisions for high-risk AI Systems

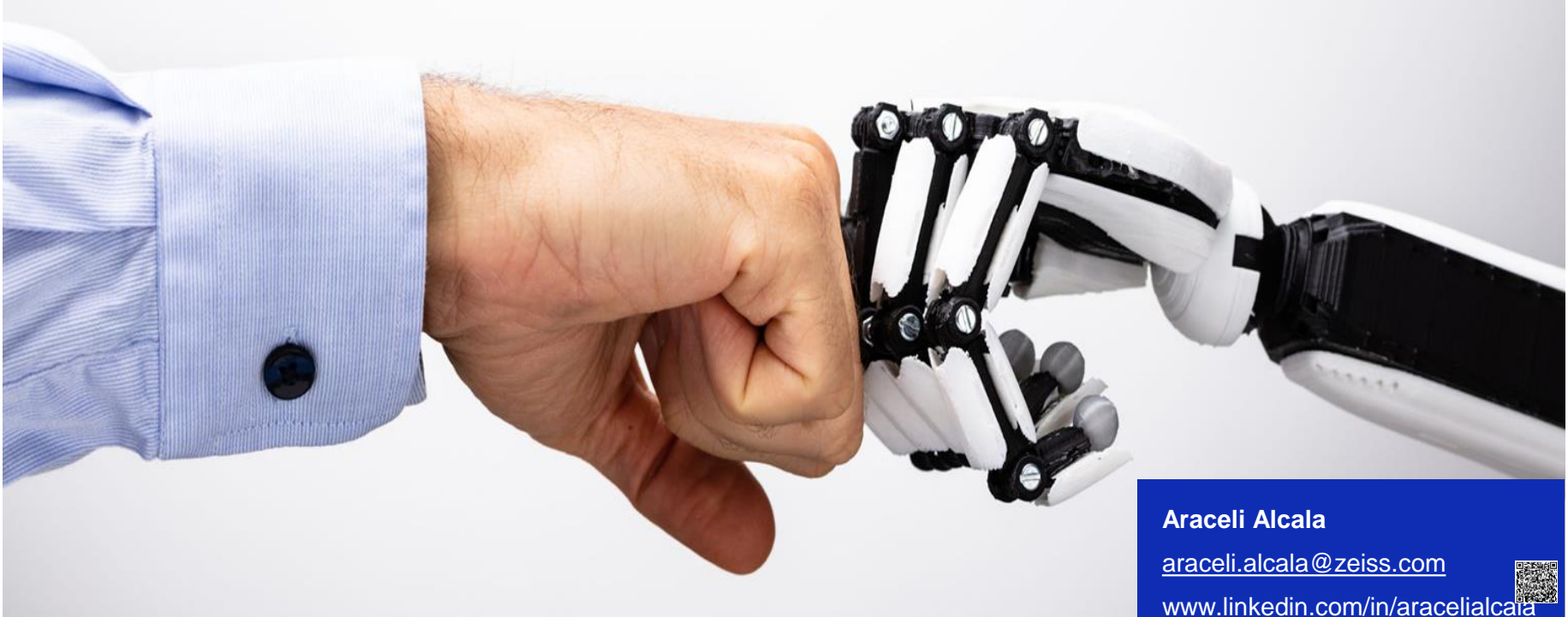


- Fully covered
- Partially covered
- Not covered



1. **Early preparation** is crucial
2. Stronger clinical **evidence** is essential
3. Post-market surveillance (PMS) is a **continuous journey**
4. Proper resource allocation
5. Compliance is a **cross-functional effort**
6. **Tailor** the QMS

Thank you



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Seeing beyond



03:45 - 04:05 pm

# Talk: GPAI Model Fine-tuning

Maximilian Kufner - BMW





04:05 - 04:25 pm

# Talk: Transparency Obligations: AI Use Cases

**Sebastian Grantz**

Global Data & Privacy Manager, Industry Relations, Google Germany

BMW  
GROUP



# REGULATORY RESPONSIBILITIES IN THE CASE OF GPAI MODEL FINE TUNING

MAXIMILIAN KUFNER, BMW GROUP

# THERE ARE DIFFERENT REQUIREMENTS FOR PROVIDERS OF GPAI MODELS WITH AND WITHOUT SYSTEMIC RISK.

10<sup>25</sup> FLOPS or **less** used for the training



## Requirements for GPAI models **without** systemic risk

**Article 53:** Obligations for providers of GPAI models, esp.:

- **Technical documentation** (s. Annex XI (1) for minimum requirements)
- **Copyright compliance strategy**
- **Information and documentation for providers of AI systems** (s. Annex XII for minimum requirements).
- **Training data**

➤ **“Documentation Obligations”**

**More than 10<sup>25</sup> FLOPS** used for the training



## Requirements for GPAI models **with** systemic risk

**Art. 53 (1), Annex XI (2):** Additional information to be provided by providers of GPAI models with systemic risk, esp.:

- **Evaluation strategies**
- **Adversarial testing**
- **System architecture**

**Article 55:** Obligations of providers of GPAI models with systemic risk, esp.:

- **Model evaluation, risk assessment and mitigation**
- **Incident tracking, documentation and reporting**
- **Cybersecurity protection**

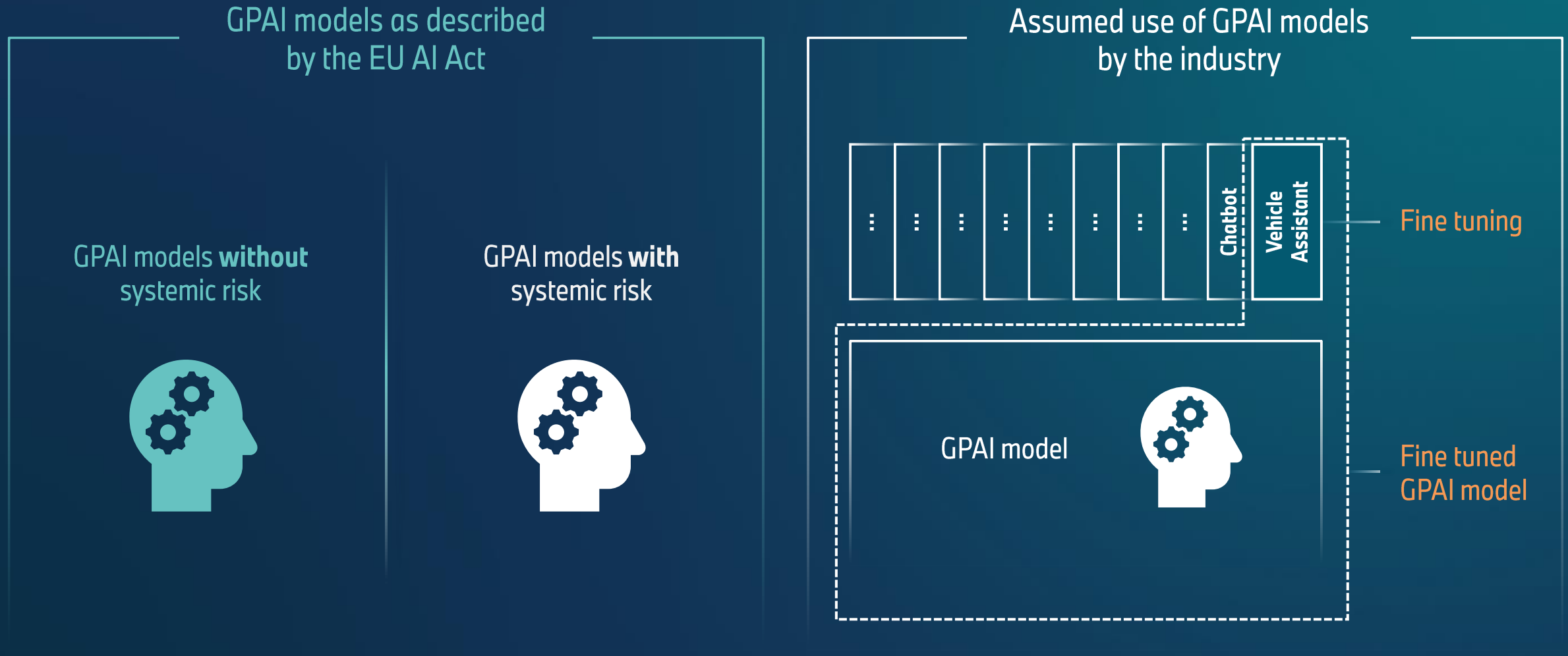
➤ **“Integrity Obligations”**

Additional requirements for AI models with systemic risk:



There are **“Documentation Obligations”** and **“Integrity Obligations”** for GPAI models.

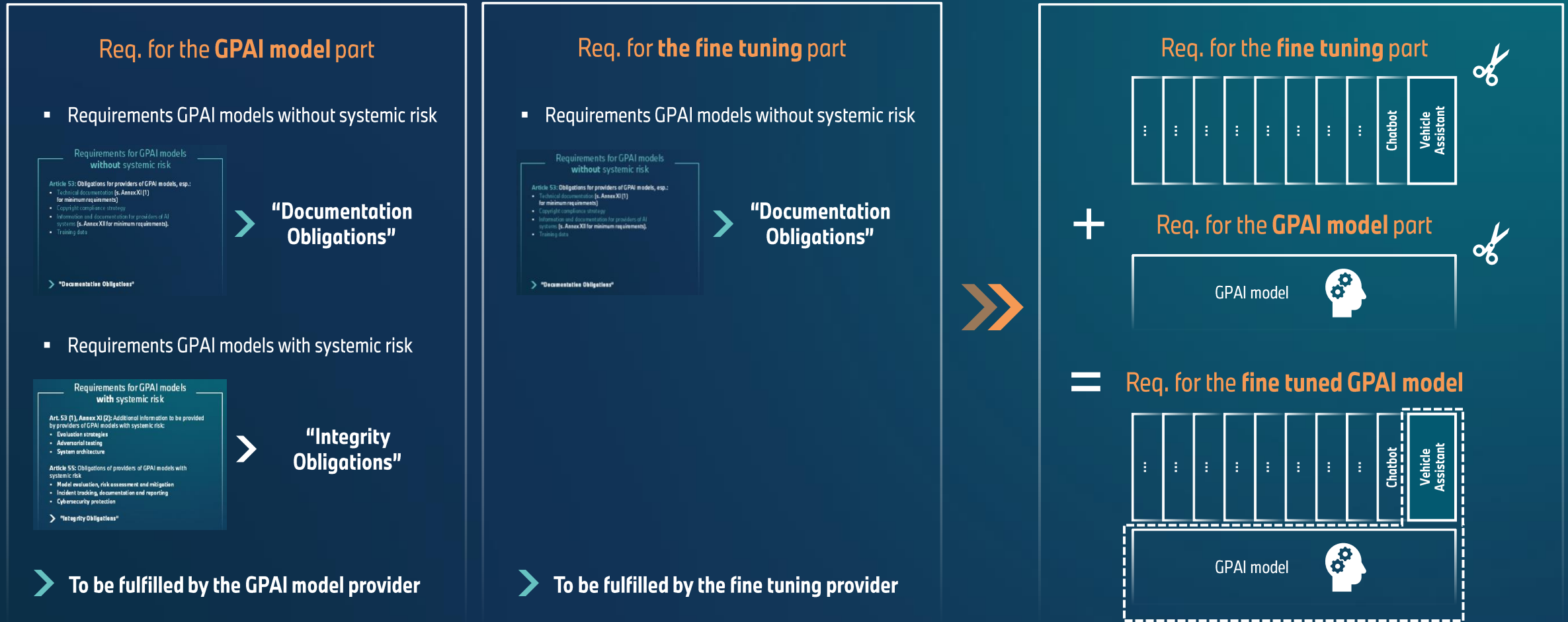
# THE EU AI ACT DEFINES GPAI MODELS AS MONOLYTIC. IN REALITY INDUSTRIAL APPLICATIONS WILL APPLY FINE TUNING.



Obligations for GPAI models mentioned in the EU AI Act do **not consider fine tuning** and are **hardly applicable** for the industry.



# THERE ARE MULTIPLE OPTIONS REGARDING RESPONSIBILITIES FOR FINE TUNED GPAI MODELS. ONLY SHARED RESPONSIBILITY SEEMS APPLICABLE.



**Proposal:** The requirements for fine tuned GPAI models are solely the sum of the requirements for the GPAI model and the requirements for fine tuning.

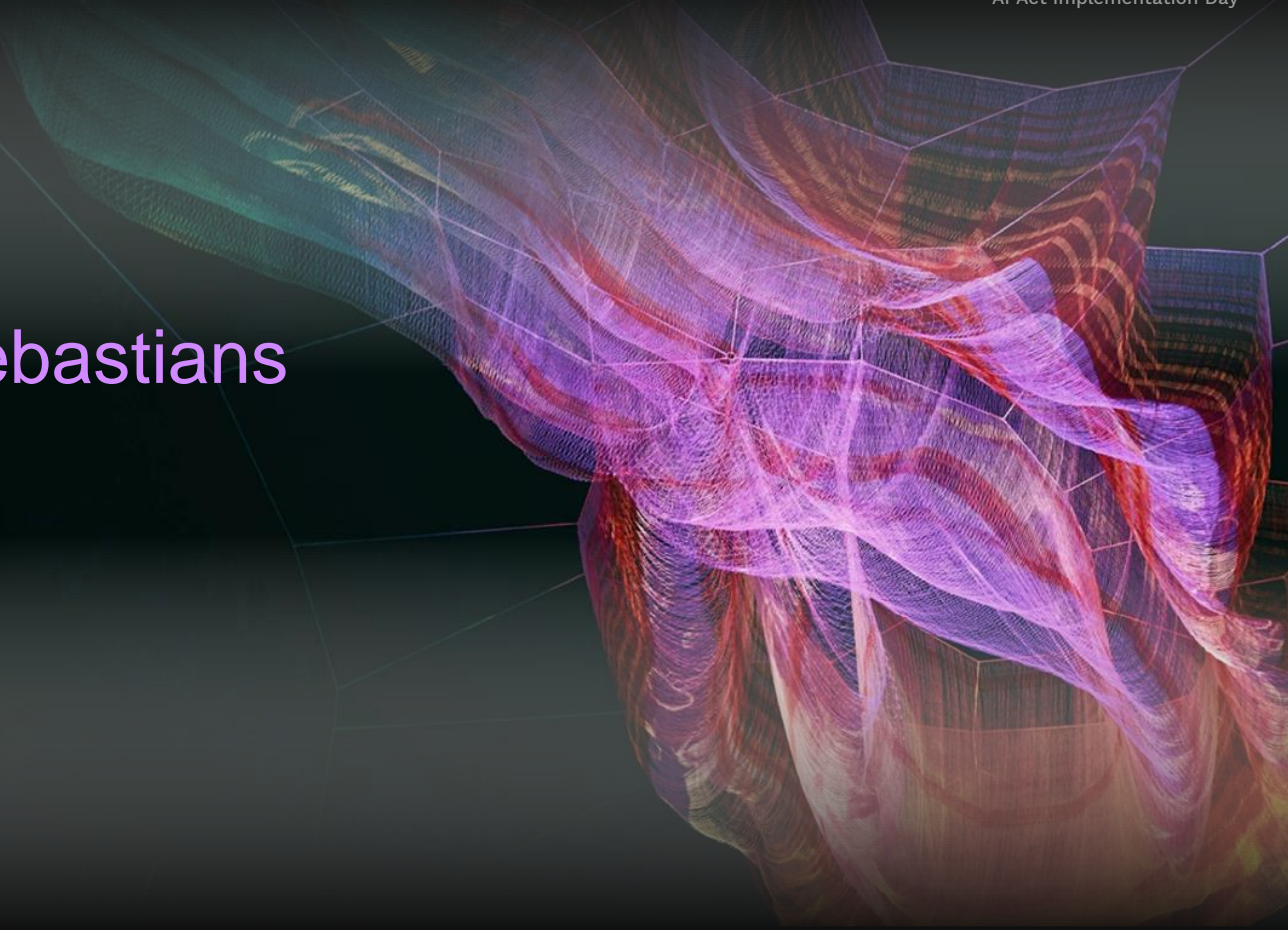
THANK YOU FOR  
YOUR ATTENTION!



Please find Sebastians  
content here:

[Post](#)

[White paper](#)



04:25 - 04:45 pm

# Talk: AI Literacy requirements and how to meet them

**Paula Cipierre**

Director of Data Ethics & Innovation, ada Learning

# AI Act Implementation Day

13.02.2025

ada

## AI Literacy As Defined By Art. 4 AI Act

Core Requirements & Best Practices for Implementation




**Paula Cipierre**


Director of Data Ethics & Innovation  
ada Learning GmbH

# Introduction

# Introduction (1/2)

 In February 2025, Art. 4 AI Literacy became applicable as one of the first requirements of the EU AI Act.

! Art. 4 AI Act requires that all organizations developing or deploying AI in the EU take reasonable measures to ensure a **sufficient level of AI literacy** of their staff and other persons handling AI systems on their behalf.

 The AI Act defines AI literacy as the ability to make an **informed deployment** of AI systems, and to gain awareness about their **opportunities, risks, and possible harms**.

✓ In so doing, organizations have to take into account their employees' **background and role**, the **context** in which the AI systems are to be used, and the **perspective of affected persons**.

# Introduction (2/2)

💡 In other words, Art. 4 AI Literacy encompasses the following three components:

- 1 **Legal knowledge** (a sufficient level of AI literacy).
- 2 **Technical knowledge** (the ability to make an informed deployment of AI systems).
- 3 **Role- and context-specific knowledge** (taking into account the background and role of employees, the context the AI systems are to be used in, and the perspective of affected persons).



# Core Requirements

# Legal knowledge

- 1 Employees should be able to recognize when they are interacting with an AI system as defined by the AI Act.
- 2 Employees should understand the role their organization plays with regards to the AI system and in particular if it operates as a provider or deployer.
- 3 Employees should be able to evaluate the opportunities, risks, and possible harms of AI systems.
- 4 Employees should have basic familiarity with the concept of high-risk AI systems.

# Technical knowledge

💡 Employees need to be able to make an **informed deployment** of AI systems.

➔ In other words, organizations should ensure that their employees know how to use the AI systems that are made available to them.

✅ Note that this is not only a compliance requirement, but also a business advantage.

# Role- and context-specific knowledge

💡 When implementing AI literacy, organizations have to take into account their employees' **background and role**, the **context** in which the AI systems are to be used, and the **perspective of affected persons**.

! Beyond foundational knowledge, companies may thus have to invest in **additional trainings for specific groups of employees**.

➔ What additional trainings to offer could depend on the **role** the organization is playing with regards to its AI systems (provider or deployer) and the **type** of AI systems it operates (high-risk or not).

# Best Practices for Implementation

# Best practices for implementation

✓ **Legal knowledge**: Familiarize your employees with relevant concepts of the AI Act.

- Definition of AI systems
- Roles and responsibilities along the lifecycle of AI
- Opportunities, risks, and possible harms of AI
- High-risk AI systems

✓ **Technical knowledge**: Create an inventory of AI systems, including who has access to which system, and train your employees how to use them accordingly.

✓ **Role- and context-specific knowledge**: Invest in further AI literacy measures depending on the organization's role (provider or deployer) and the nature of the AI systems (high-risk or not).



# Frequently Asked Questions (FAQs)

# FAQs

→ What fines are associated with non-compliance?

✓ There are no direct fines associated with non-compliance with Art. 4 AI Act.

→ Why should I bother implementing Art. 4 AI Act in that case?

✓ First, because it is a legal requirement regardless. Second, because you don't want to be in the awkward position where your AI systems cause harm, and it then turns out you did not train your employees appropriately. Third, the likelihood that your AI systems do cause harm is inevitably lower if your employees know how to use them effectively and ethically.

→ I have not yet started implementing Art. 4 AI Act. Am I in trouble?

✓ Not yet. In an AI Pact workshop on AI literacy in December 2024, the European AI Office suggested enforcement of AI literacy would not begin before August 2025.

→ I still have questions. Where can I find out more?

✓ The European AI Office will be hosting a webinar on AI literacy on February 20th from 10am-12pm.

Thank you

ada

## Paula Ciperre

Director of Data Ethics & Innovation



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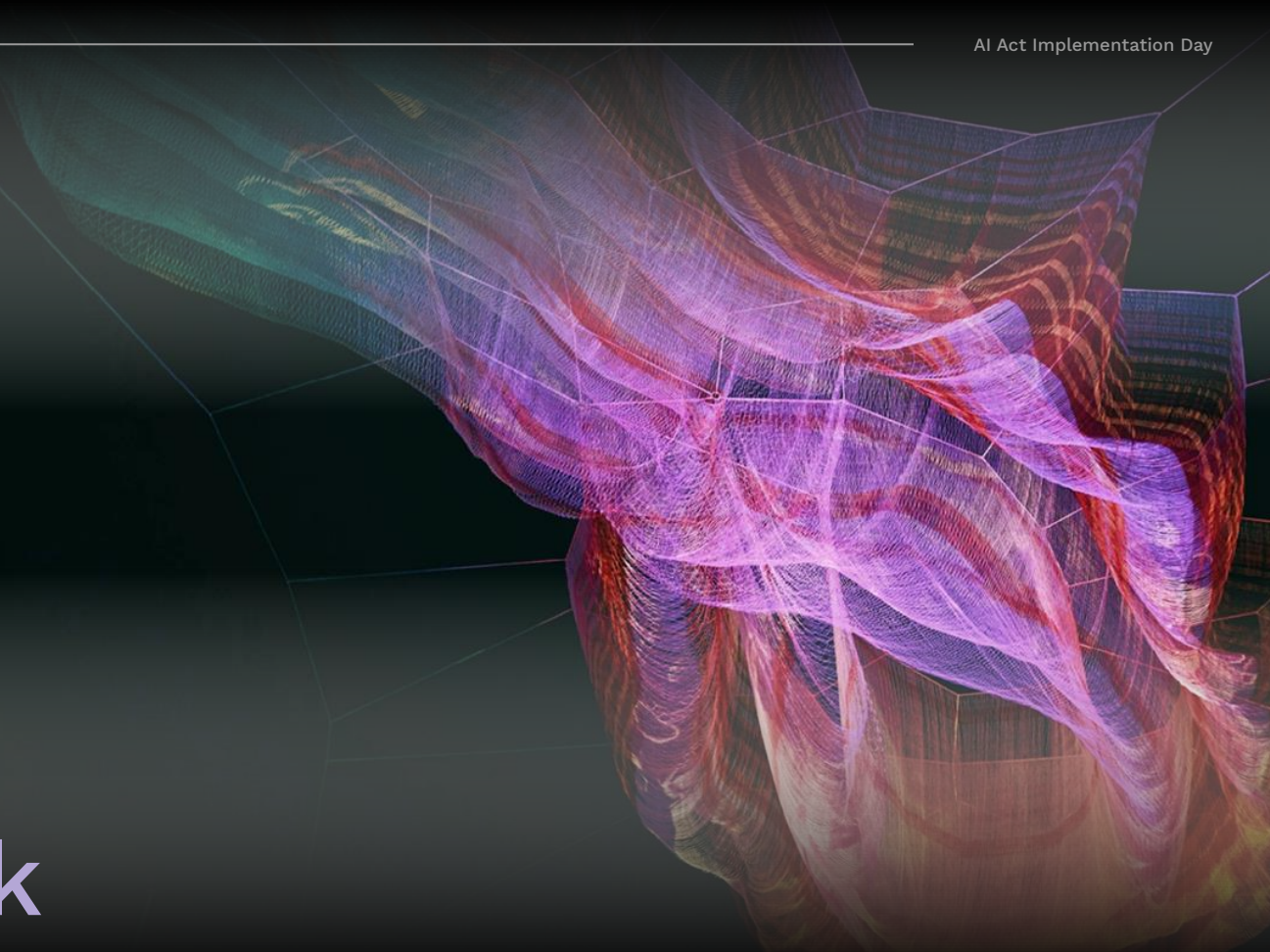
The logo features the word "ada" in a lowercase, black, sans-serif font. The letters are centered and partially overlaid by several organic, rounded shapes. A large, bright yellow shape is on the left, with a smaller yellow circle to its right. To the right of the yellow shapes are several grey shapes of varying sizes, including a large one at the top right and a smaller one below it. A small yellow circle is positioned at the bottom right of the main cluster of shapes.

ada

GROWTH RARELY HAPPENS ALONE.

04:45 - 05:05 pm

# Closing Remarks & Outlook



# Dr. Till Klein

Head of AI Regulation  
appliedAI Institute for Europe





# Launching soon: AI Act Essentials Online Course

## A collaboration with KI-Campus and TUM



KI-Campus-Original

## EU AI Act Essentials

Noch keine Bewertungen  vorhanden



ca. 12 Stunden



Leistungsnachweis



Einsteiger:innen



Kostenlos

[Einschreiben / Zum Kurs](#)



Dieser Kurs wird angeboten von

Lernangebote / EU AI Act Essentials

## Überblick



# The **Bavarian AI Act Accelerator** is speeding up compliance with the AI Act while fostering AI Innovation

## Mission

Accelerating the process of **AI Act compliance** by **linking research and practice** through the systematic identification of the **biggest challenges** facing businesses and public bodies and addressing them through new and existing services.

## Objectives

1. Reduce compliance cost
2. Shortening time to compliance
3. Strengthening AI Innovation

## Target groups

1. Startups
2. Small and medium sized enterprises
3. Public sector



Bayerisches Staatsministerium  
für Digitales



This project is funded by the Bavarian Ministry for Digital Affairs.



# Thank you!

