

ACC Deal or No Deal

EU AI Act

Simmons & Simmons



# Introduction



# Speakers and Agenda



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## Agenda

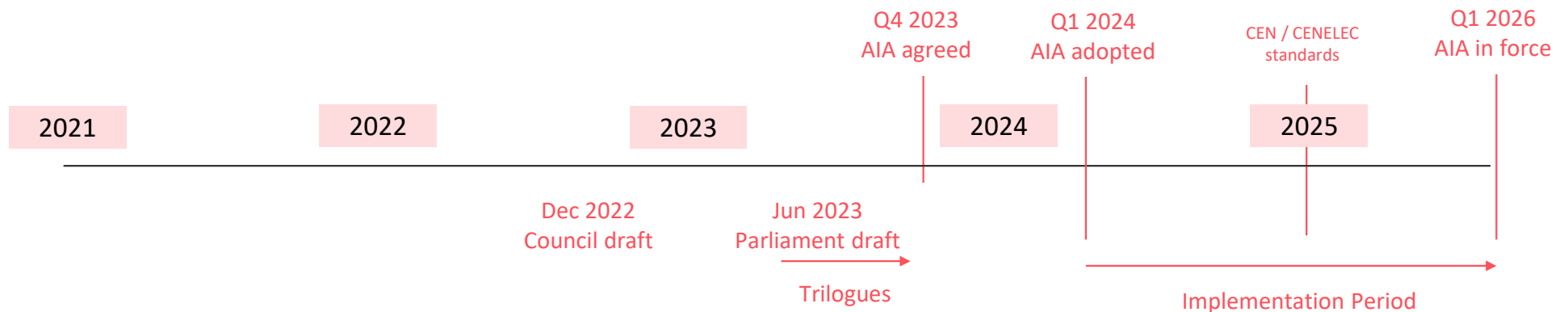
- Introduction to the EU AI Act
- Case studies: application to US companies
- AI implementation challenges
- Interaction with GDPR
- Q&A

# Introduction to the EU AI Act



# Origins and latest status

- In 2019, President von der Leyen promised EU regulation on AI. **European Commission** published draft AIA in **Apr 2021**, following white paper.
- **European Parliament** adopted amendments to draft AIA on **14 Jun 2023**, following **European Council's** proposed amendments in **Dec 2022**
- **Final AIA text** now being **negotiated** (so-called 'trilogues')
- Timeline, with anticipated future steps:



# Key points

- **Binding regulation**, following EU's 'New Legislative Framework' for product safety, comprising **harmonised requirements**, **certification**, **market monitoring rules** and **enforcement** through EU and Member State bodies
- **Horizontal** application, with **risk-based approach**
- Focus on **risky uses**, but also now on **risky forms of AI technologies**
- **Substantive** and **procedural** obligations
- **Regulatory burden** higher on **providers / developers** than on users / deployers
- **Extra-territorial**
- EU enforcement network with **high fines** for non-compliance

# Definition of “AI system”

## Commission Draft

AI system means software that is developed with one or more of the techniques and approaches listed in Annex I 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.

...

(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.

## Council Proposal

AI system means a system that is designed to operate with **elements of autonomy** and that, based on machine and/or human-provided data and inputs, infers how to achieve a **given set of objectives** using machine learning and/or **logic- and knowledge based approaches**, and produces system-generated outputs such as **content (generative AI systems)**, predictions, recommendations or decisions, influencing the environments with which the AI system interacts.

## Parliament Text

AI system means a machine-based system that is designed to operate with **varying levels of autonomy** and that can, for **explicit or implicit objectives**, generate outputs such as predictions, recommendations, or decisions that influence physical or virtual environments.

# Stakeholders

## Provider

(developer of an AI system- a natural or legal person, authority, institution or other body)

## Importer

(physically present or established in the EU; places AI systems from companies outside the EU on the EU market)

## Distributor

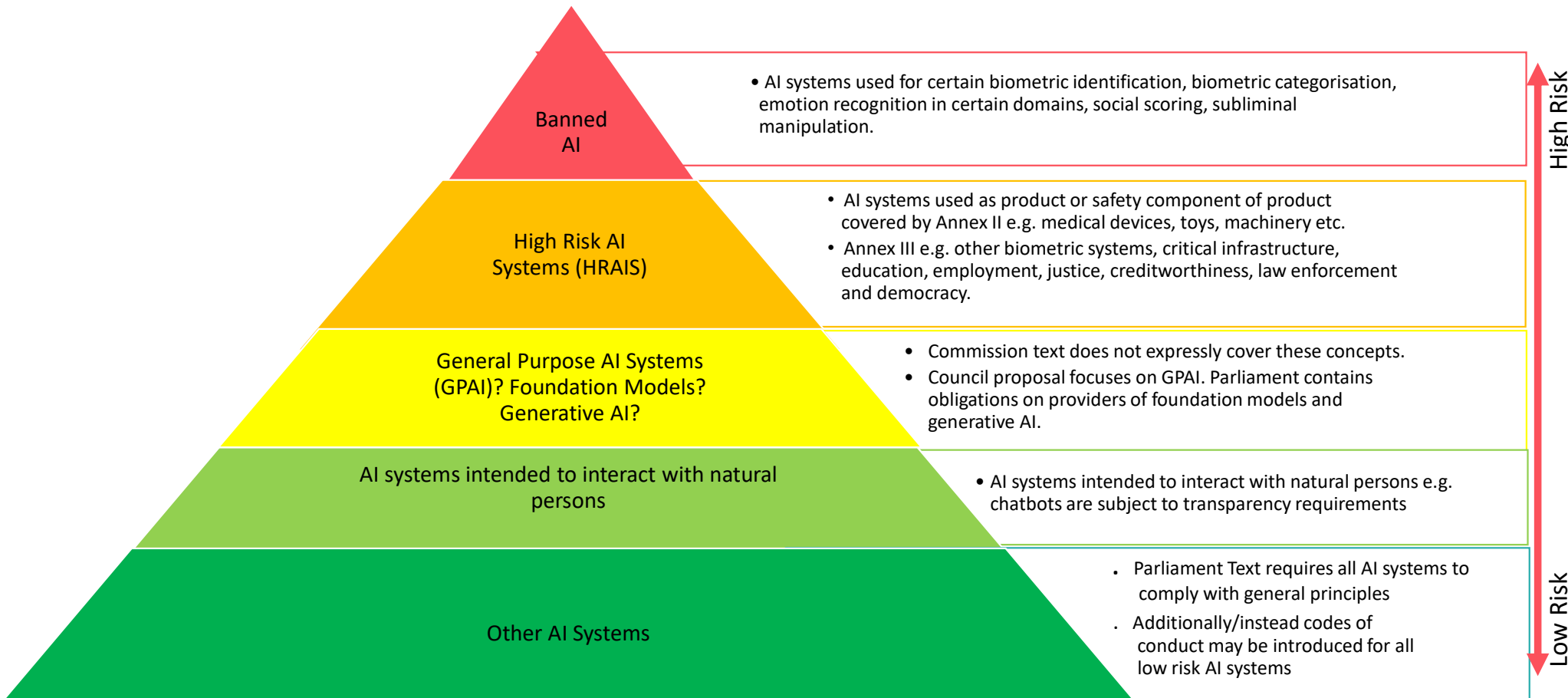
(makes an AI system available in the EU and is neither a supplier nor an importer)

## Deployer

(natural or legal person, etc., under whose responsibility AI system is used)



# Risk-based approach



# Extra-territoriality

- Act will apply to
  - users of AI systems located within the EU
  - providers placing on the market or putting into service AI systems in the EU, even where they are established outside of the EU
  - providers and deployers of AI systems that are located outside of the EU, where the “output produced by the system is used in the [EU]”



# Stakeholders – Obligations

## Provider

(developer of an AI system- a natural or legal person, authority, institution or other body)

## Deployer

(natural or legal person, etc., under whose responsibility AI system is used)

# Provider obligations re high-risk AI systems (Art. 16)

## Risk management

Implementing process for entire lifecycle of HRAIS to identify, analyse and mitigate risks

*Article 9*

## Data quality / Data Governance

Training and testing of HRAIS using data shall be undertaken in accordance with

*Article 10*

## Technical Documentation

Drafting comprehensive "manual" for HRAIS which contains, at a minimum the Annex IV information

*Article 11*

## "Record-keeping"

HRAIS must be designed to ensure automatic logging of events eg period of use and input data reviewed (Article 12) and providers must keep these logs

*Article 20*

## Transparency / Explainability

HRAIS must be accompanied by instructions for use which include detailed information including their characteristics, capabilities and limitations, *Article 13*

## "Human oversight"

HRAIS must be designed so they can be overseen by humans, who should meet various requirements eg being able to understand the HRAIS and to stop its use

*Article 14*

## Accuracy, resilience and cyber security

HRAIS must be accurate (with accuracy metrics included in instructions for use), resilient to errors or inconsistencies (eg through fail-safe plans) and resilient to cyber-attacks

*Article 15*

## Quality - Management Systems

HRAIS providers must put in place a comprehensive quality management system which includes at least the extensive information requirements

*Article 17*

## Conformity assessment

HRAIS provider shall follow conformity assessment procedure

*Article 43*

## "Post-marketing monitoring"

HRAIS providers must document a system to collect and analyse data provided by users on the performance of the HRAIS throughout its lifetime

*Article 61*

# Provider obligations re high-risk AI systems

Data quality / Data  
Governance

Training and testing of  
HRAIS using data shall  
be undertaken in  
accordance with

*Article 10*

## Key provision!

- Training data = basis of any AI System
- Insufficient quality of training data:
  - Negative impact on functioning of AI System
  - Output may be incorrect
  - Bias as a result

# Sanctions: Violation of Provider obligations

- ❑ Violation of provider obligations "**Data Quality**" (Art. 10) and "**Transparency**" (Art. 13)

up to

- EUR 20 million or, in the case of a company,
- 4 % of the annual worldwide turnover of the previous marketing year

- ❑ Violation of **any other provider obligation** (listed in Art. 16):

up to

- EUR 10 million or, in the case of a company,
- 2 % of the annual worldwide turnover of the previous marketing year

# Stakeholders – Obligations

## Provider

(developer of an AI system- a natural or legal person, authority, institution or other body)

## Deployer

(natural or legal person, etc., under whose responsibility AI system is used)

# Obligations for Deployers of high-risk AI systems (Art.29)

## ❑ "AI Literacy" (Art. 4b)

- Teaching basic notions & skills about AI systems, risks & benefits to staff
- "Sufficient level of AI literacy" = ability of deployer to ensure compliance with AI Act

## ❑ Compliance with "General Principles" (Art 4a)

- e.g. compliance with GDPR / continuous monitoring / event logging

## ❑ "Fundamental rights impact assessment" prior to putting system into use (Art. 29a)

- Intended purpose of use
- Categories of natural persons to be likely affected
- Reasonable foreseeable adverse impact of use of system
- Description of governance system (incl. human oversight)
- Detailed plan on risk mitigation

Jointly with  
Art. 35 GDPR  
Data Protection  
Impact Assessment  
(where applicable)



# Sanctions: Violation of Deployer obligations

## Violation of any deployer obligation:



up to

- EUR 10 million or, in the case of a company,
- 2 % of the annual worldwide turnover of the previous marketing year

# Foundation Models (GPT-4 et al)

## □ Foundation models:

- **all models:** transparency obligations
- **"very capable" models:** red-teaming through vetted red-testers, risk assessment/mitigation and regular compliance controls through independent auditors.
- **"very capable" models:** threshold to be introduced that triggers (rebuttable) assumption that model is "very capable" (e.g. compute power used to train model in FLOPS)

## □ Copyright:

### Providers must:

- **respect rights holders' opt-out right** from content to be used for training purposes
- **make publicly available** sufficient detailed summary re content used for training & policies to manage copyright-related aspects

# General Purpose AI (ChatGPT et al)

## GPAI systems:

### □ all provider of GPAI systems:

- explicit statement whether GPAI can be used for high-risk uses.
- where high-risk is excluded: measures to detect and prevent such use need to be introduced.
- where high-risk is allowed: GPAI system needs to comply with requirements for high-risk AI systems.

### □ GPAI systems used "at scale" in EU:

- subject to regular red-teaming through vetted red-testers & risk assessment/mitigation.

### ❖ GPAI system used "at scale"?

- impact and reach relevant.
- relevant threshold proposed: 10,000 registered business users (i.e. developers) or 45 million registered end users.

(Note for comparison: ChatGPT has currently approx. 100+ million end users.)

# Enforcement of the AI Regulation/Sanctions

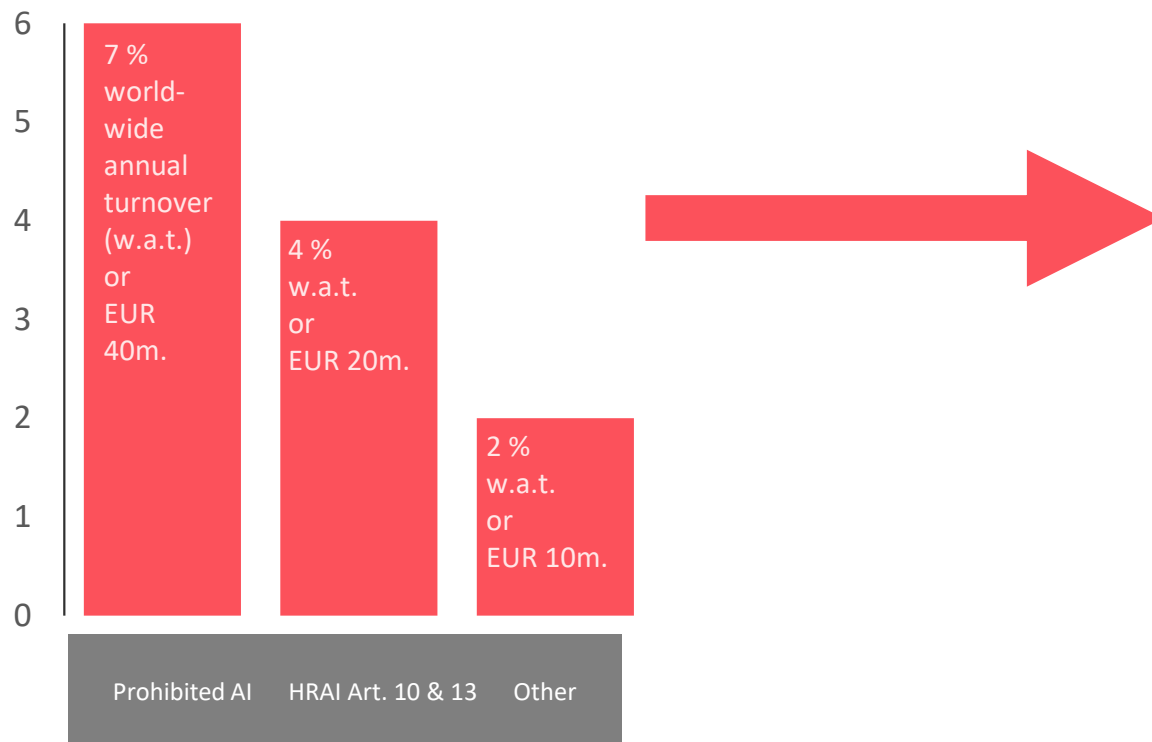
- ❑ **National authorities** (to be determined by each EU member state)
- ❑ New "**AI Office**" (hosted within EU Commission)
  - EU-wide enforcement of new rules on foundation models & GPAI systems

*"Being the first body worldwide with powers to enforce rules on foundation models and GPAI, the AI Office would become an international reference point for AI governance."*

# Liability

- Sanctions, Art. 71 AI Act.

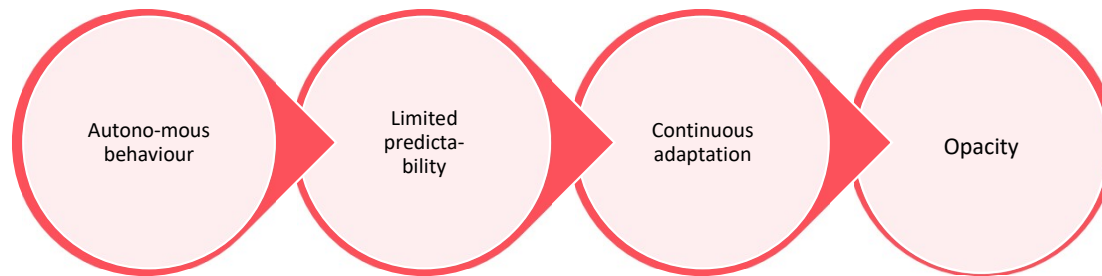
- Civil liability?



But...

# Adaption of liability regulations to the digital age

EU Commission: **Characteristics of AI** make it difficult to claim damages



**Further:** "Costly to prove **damage** and **causality** (due to lack of technical expertise)"  
(→ burden of proof on side of claimant!)

**28 September 2022:**

➤ EU Commission proposed an EU **Directive** adapting the rules on **civil liability to artificial intelligence** (AI Liability Directive)

# AI Liability Directive (draft)

Easier to enforce damage claims in respect of  
High-risk AI systems

Broad disclosure obligations  
**for providers/deployers of AI  
systems alleged** to have inflicted  
harm  
(reversal of burden of proof!)

if no disclosure:  
(rebuttable)  
presumption of fault

(rebuttable)  
presumption of a causal link  
in event of a  
**fault**

"Fault" on the side of provider if:

- Data quality (-)
- Transparency (-)
- Cybersecurity (-)

"Fault" on the side of deployer if:

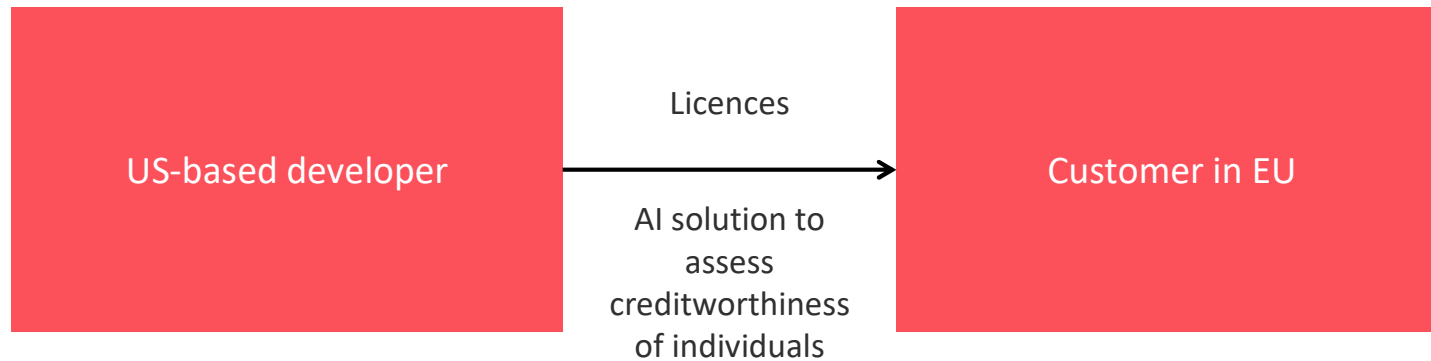
- Used according to instructions for use (-)
- Input data contradict purpose

# Case Studies





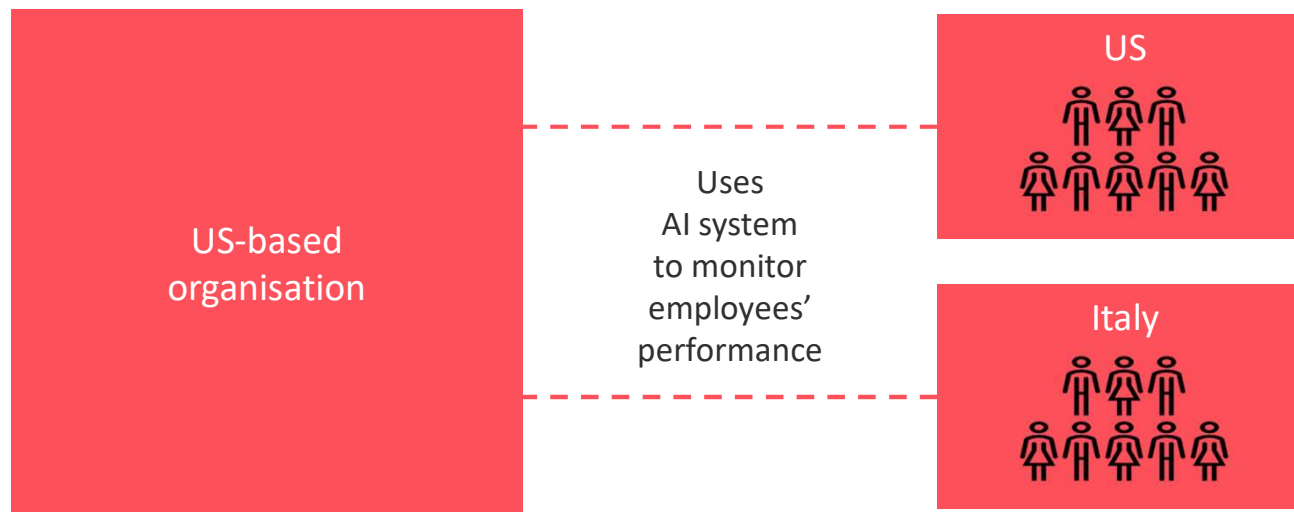
# Case study 1: US developer



"placing on the market ... AI systems in the EU, even where they are established outside of the EU"

Article 2(i)(a)

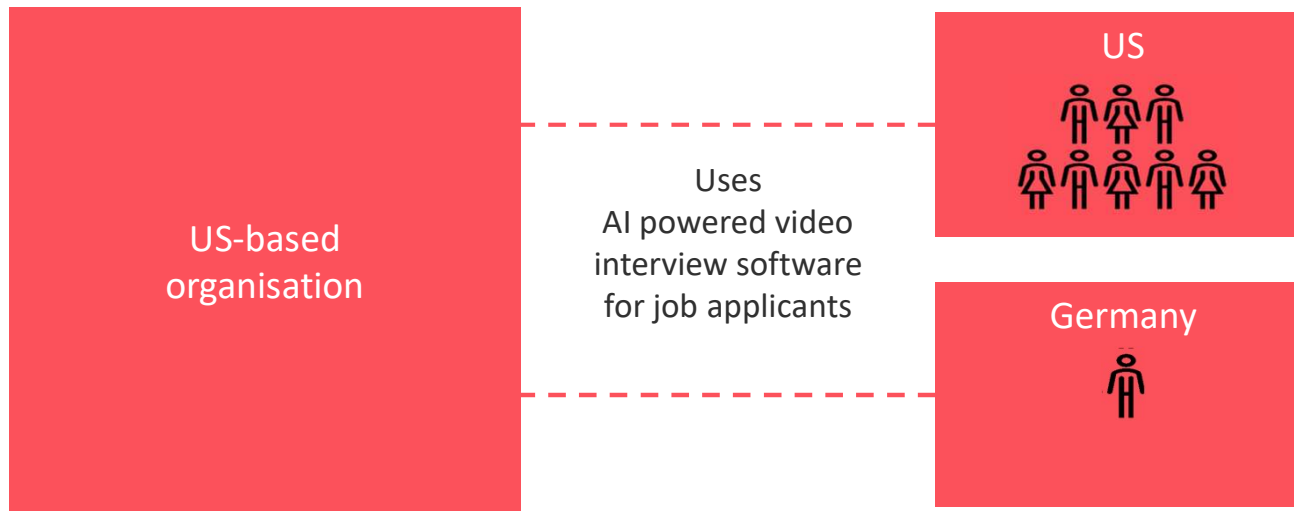
## Case study 2: US deployer with EU Employees



"deployers of AI systems that are established / located outside of the EU, where the output produced by the system is used in the EU"

Article 2(i)(c)

# Case study 3: US deployer with EU applicants



"deployers of AI systems that are established / located outside of the EU, where the output produced by the system is used in the EU"

Article 2(i)(c)

# AI implementation challenges



# Interaction with GDPR



# GDPR - Key Considerations

- Scope of **personal data processed** and **applicability** of GDPR
- **Legal basis** for processing (Art. 6 and 9)
- **Transparency** and information provision (Art. 12–14)
- **Automated decision making** and profiling (Art 22)
- **Security** (Art. 32-34):
  - ensuring appropriate levels of security against its unauthorised or unlawful processing, accidental loss, destruction or damage;
  - compliance with breach notification requirements
- **Data privacy impact assessments** (Art. 35)
- Responsibilities and requirements when **using data processors** (Art. 28)

# International Data Transfers

International data transfer requirements under the UK GDPR/EU GDPR:

- Transfers of personal data to third countries (i.e. non-UK / EU countries) may only be made when there is a valid legal mechanism legitimizing the transfer.
- Valid legal mechanisms include:
  - A finding of **adequacy** in relation to that third country or international organisation, e.g EU-US Data Protection Framework and UK-US Data Bridge;
  - **Standard Contractual Clauses (SCCs)** being agreed between the data exporter and data importer;
  - **Binding Corporate Rules** being approved and implemented; or
  - Limited **derogations for specific situations**.
- Where personal data is being transferred between the UK / EU and the US, one of the above mechanisms is required.

# Q&A





The background is a complex digital network of glowing blue and red lines and dots, resembling a data mesh or a stylized globe. The lines are thin and connect various points, creating a sense of interconnectedness. The colors transition from deep blue at the top to a vibrant red at the bottom, with some purple and pink hues in the lower sections. The overall effect is futuristic and high-tech.

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