

EU AI Act: Standards and Tools – Key for Compliance

AI Trust in Electronics Summit
Oslo, 4 September 2025

Overview

The EU AI Act – EU
Technical Regulation:
Where are we?

Areas of Regulation:
General Purpose AI
Models, High-Risk AI
Systems

Standards – State of
Play and Outlook

Tools

Typical EU Market Access and Safety Regulation

2024/1689

12.7.2024

REGULATION (EU) 2024/1689 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

(Text with EEA relevance)

Scope

Promote the uptake of human centric and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety, fundamental rights

Harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems')

Prohibitions of certain artificial intelligence practices;

Specific requirements for high-risk AI systems and obligations for operators of such systems;

Harmonised transparency rules for certain AI systems;

Harmonised rules for the placing on the market of general-purpose AI models.



What characterises a
“typical EU Technical
Regulation” ?

Who is that ?



Jacques Delors

* 20. Juli 1925

† 27. Dezember 2023

Former president of the European Commission (1985-1995)

Major role in overcoming the “europsclerosis” of the 1980s and accelerating the process of strengthening European unity (EEA, Maastricht treaty, re-organising the European Commission)



And why is he
of relevance
for our topic...?



50:50

15	€1 MILLION
14	€500.000
13	€125.000
12	€64.000
11	€32.000
10	€16.000
9	€8.000
8	€4.000
7	€2.000
6	€1.000
5	€500
4	€300
3	€200
2	€100
1	€50

During Jacques Delors's term of office as President of the European Commission he

A: Ordered that regulations should be written like standards

B: Introduced a law entitling the European Parliament to set technical standards

C: Introduced the legal framework of the New Approach

D: Required EU Member States to set up national Standardisation Bodies

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C: Introduced the legal framework of the
New Approach

D:

AI Act – EU technical regulation

IBM has decades-long experience in working with such regulations in the field of hardware compliance, e.g. product safety, electromagnetic compatibility, etc.

Basic Principle (“EU New Legislative Framework” formerly New Approach):

Legislators

Legal acts lay down the essential requirements and define safety objectives.

Private Sector

Harmonised European Standards define the technical way how to fulfil the legal requirements and be compliant with the safety objectives.

Compliance is mandatory for market access.

Harmonised standards are developed in one or more of the European standardisation organisations and are based on formal EU standardisation requests.

The New Approach / New Legislative Framework: Before and After

BEFORE

All technical requirements were part of the legal acts.



AFTER

Legal acts lay down the legal requirements and define safety objectives.

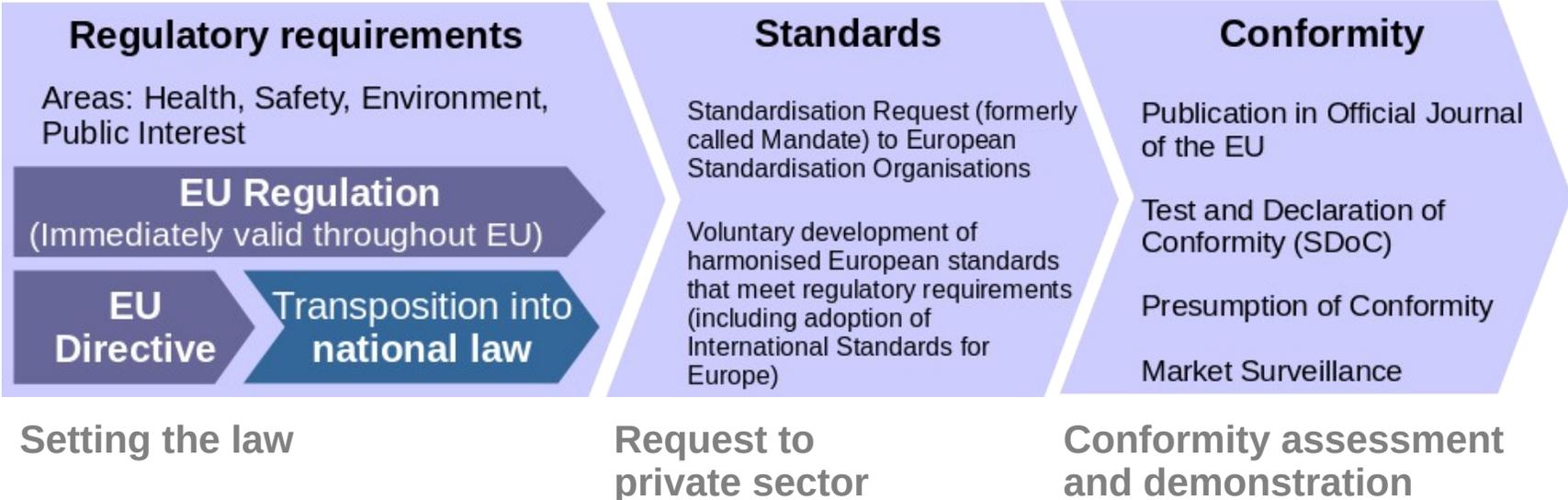
Harmonised European Standards define the technical way how to fulfil the legal requirements and be compliant with the safety objectives.

New Legislative Framework (NLF): Key Role for Standards

- Key element of the EU regulatory framework and the EU single market
- Definition of safety objectives in legal acts, technical details laid down in standards
- Standards development on the basis of an EU Standardisation Request
- Compliant products may be brought to the market in the EU under the presumption of conformity
- Innovation friendly – innovation via standards

EU Legislators
**REGULATION/
DIRECTIVE**

Industry and other stakeholders
STANDARDS



AI Act: Key Role of Standards

Article 40 establishes the processes of the EU New Legislative Framework to be used.

A Supplier's Declaration of Conformity testifies compliance and allows to bring and operate technologies on the market.

No 3rd party certification required.

Article 40

Harmonised standards and standardisation deliverables

1. High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.

EU AI Act: Requirements

Prohibited practices

Applies 6 months after AI Act coming into force, i.e. February 2, 2025.

General purpose AI

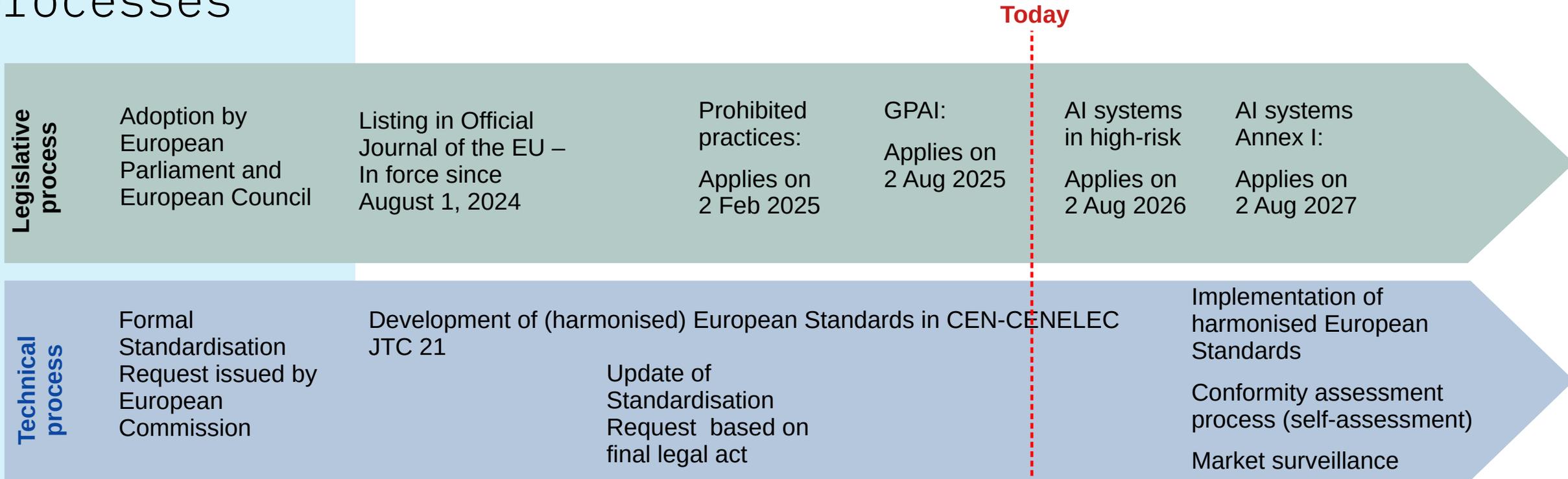
Applies 12 months after AI Act coming into force, i.e. August 2, 2025.

AI systems in high-risk areas

For areas listed in Annex III: applies 24 months after AI Act coming into force, i.e. August 2, 2026.

For areas related to Annex I: applies 36 months after AI Act coming into force, i.e. August 2, 2027.

AI Act: Legislative and technical processes



GPAI:
Code(s) of practice to bridge time until harmonised standards are available

A further standardisation request will be issued on GPAI and sustainable AI

Will the EU AI Act be withdrawn, delayed, ... ?

Nemko Digital | Jul 31, 2025 8:40:40 AM | 5 min read

EU AI Act Delay Officially Ruled Out: Timeline Confirmed for Full Implementation

Commission rejects EU AI Act delay requests. August 2025 GPAI deadline approaches. Expert guidance on navigating fixed compliance timeline.

The European Commission has definitively ruled out any **EU AI Act delay**, confirming that the world's first comprehensive artificial intelligence legislation will proceed according to its original timeline despite intense lobbying pressure from the industry for postponement.

<https://digital.nemko.com/news/eu-ai-act-delay-officially-ruled-out>



Thomas REGNIER • 1st

Spokesperson for Tech Sovereignty, Defence, Space, Resea
1mo • Edited •

We take the concerns raised by the AI community and industry extremely seriously.

And we will address what we can address.

- We are preparing a Digital Simplification Omnibus package.
- We are discussing the timing for the implementation of the Code of Practice, with end-2025 under consideration.
- We are setting up an AI Act Service Desk, to help companies and offer clear guidance.

But a legal text is a legal text. Legal deadlines are legal deadlines. Adopted by our co-legislators.

The time lines are laid down in the legal act. Changing them would require a new legal proposal and agreement from the EP and the Council.

The rules and processes for prohibited AI technologies and for GPAI are settled and working. So all that is still open are the rules for high-risk AI systems.

The Commission closely follows the development of the harmonised standards and will be able to react.

Also market surveillance will play a key role in guiding the process.

https://www.linkedin.com/posts/thomas-regnier-24a05810b_we-take-the-concerns-raised-by-the-ai-community-activity-7346868389400768512-gTd_?utm_source=share&utm_medium=member_desktop&rcm=ACoAAACuCT8B_mFRc3OCvFMc4rox0B982IEjlls

Two Areas subject to Market Access Regulation

GPAI

Requirements apply since 2 Aug 2025

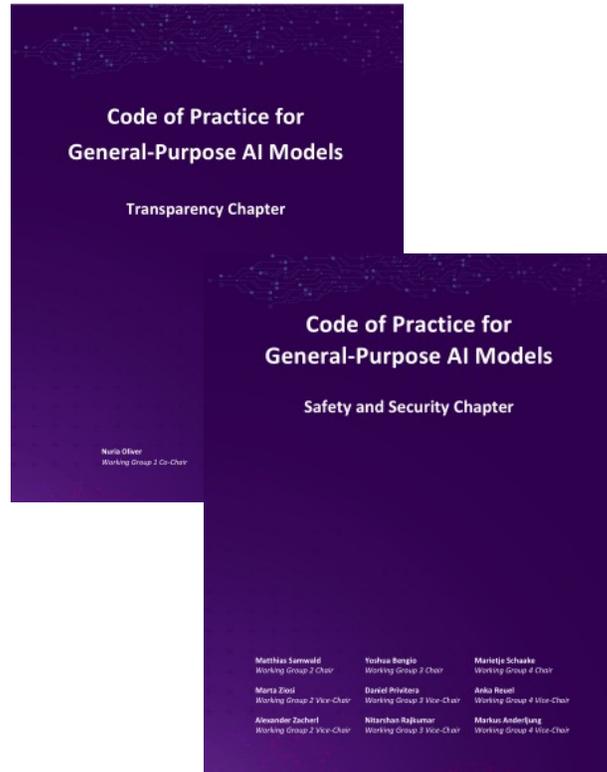
Code of Practice (CoP – done by European Commission, AI Office; stakeholders were able to comment on drafts) available.

Also available: Template for publishing openness information

IBM is an early signatory to this CoP.

On the long run: Harmonised European standards will be developed and replace the Code of Practice.

EU Code of Practice: Examples of the Requirements



Transparency

Measure 1.1 Drawing up and keeping up-to-date model documentation

Measure 1.2 Providing relevant information

Measure 1.3 Ensuring quality, integrity, and security of information

Security and Safety

Commitment 1 Safety and Security Framework

- Measure 1.1 Creating the Framework
- Measure 1.2 Implementing the Framework
- Measure 1.3 Updating the Framework
- Measure 1.4 Framework notifications

In total: 9 commitments with specific measures.

IBM Granite – performant and trusted AI models. Open Source



Open

Choose the right model, from sub-billion to 34B parameters, open-sourced under Apache 2.0.



Performant

Don't sacrifice performance for cost. Granite performance is proven across a variety of enterprise tasks.



Trusted

Build responsible AI with a comprehensive set of risk and harm detection capabilities, transparency, and IP protection.

The future of AI is Open.

<https://www.ibm.com/granite/docs/models/granite/>

IBM adopted the Linux Foundation's Model Openness Framework for assessing the models

<https://developer.ibm.com/articles/cl-open-architecture-update/>

Detailed openness information published

<https://huggingface.co/ibm-granite/granite-3.3-8b-instruct>

Model tree for `ibm-granite/granite-3.3-8b-instruct`

Base model	<code>ibm-granite/granite-3.3-8b-base</code>
Finetuned (2)	this model
Adapters	6 models
Finetunes	10 models
Quantizations	33 models

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High-risk AI Systems

Essential requirements apply by 2 Aug 2026

Currently in progress: Development of harmonised European standards according to the process of the New Legislative Framework and a Standardisation Request issued by the European Commission

Once the standards are available their correct implementation will provide presumption of conformity.

Reminder: No 3rd Party Certification required accept in exceptional cases

In the hands of the private sector

With the listing of the AI Act in the Official Journal of the EU – the legal process was done.

Development of the harmonised European Standards required for compliance is in the hands of the private sector.

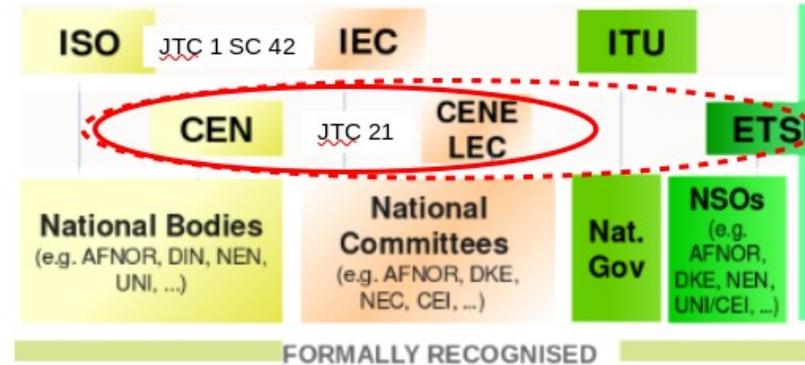
European Commission: Right of initiative for legal acts

European Council and European Parliament: Two chambers negotiating and agreeing on final legal act

LEGISLATIVE PROCESS COMPLETED WITH LISTING IN OFFICIAL JOURNAL OF EU

PRIVATE SECTOR ENTITLED TO DEVELOP HARMONISED EUROPEAN STANDARDS

Industry
Civil Society
Research
Academia
...



EU MEMBER STATES

Accreditation of notified bodies

Building up of market surveillance

CONFORMITY ASSESSMENT

Conformity assessment may be done either in the form of well documented self-assessment or in collaboration with a notified body.

Work on harmonised European standards

EU Standardisation Request in place

Risk management system for AI systems

Governance and quality of datasets used to build AI systems

Record keeping through built-in logging capabilities in AI systems

Transparency and information to the users of AI systems

Human oversight of AI systems

Accuracy specifications for AI systems

Robustness specifications for AI systems

Cybersecurity specifications for AI systems

Quality management system for providers of AI system, including post-market monitoring process.

Conformity assessment for AI systems

Expected in future Standardisation Request based on final AI Act

Sustainable AI:

"reporting and documentation processes to improve AI systems resource performance, such as reduction of energy and other resources consumption of the high-risk AI system during its lifecycle, and on energy efficient development of general-purpose AI models"

European standards supporting the transparency obligations for GPAI

Essential requirements (in the law)

Risk management system

Data and data governance

Technical documentation

Record-keeping

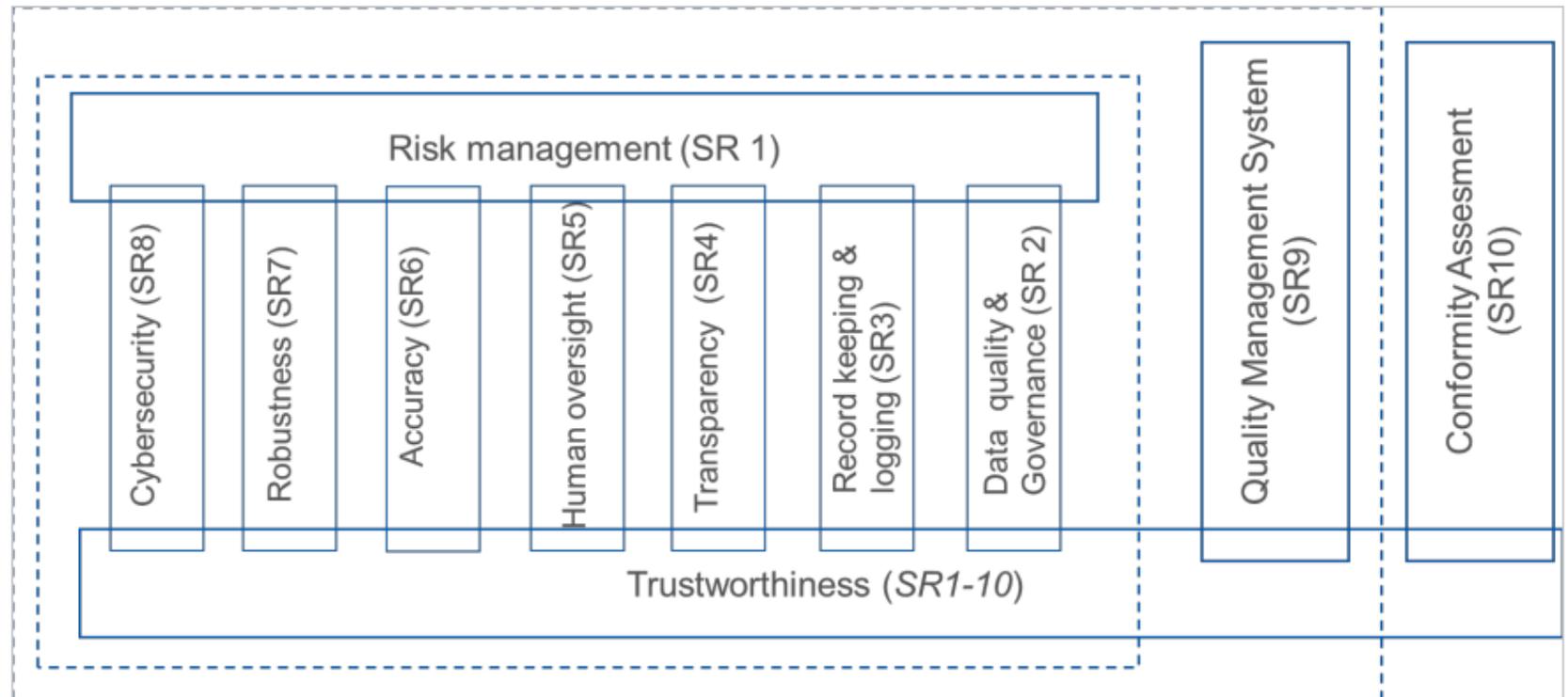
Transparency and provision of information to users

Human oversight

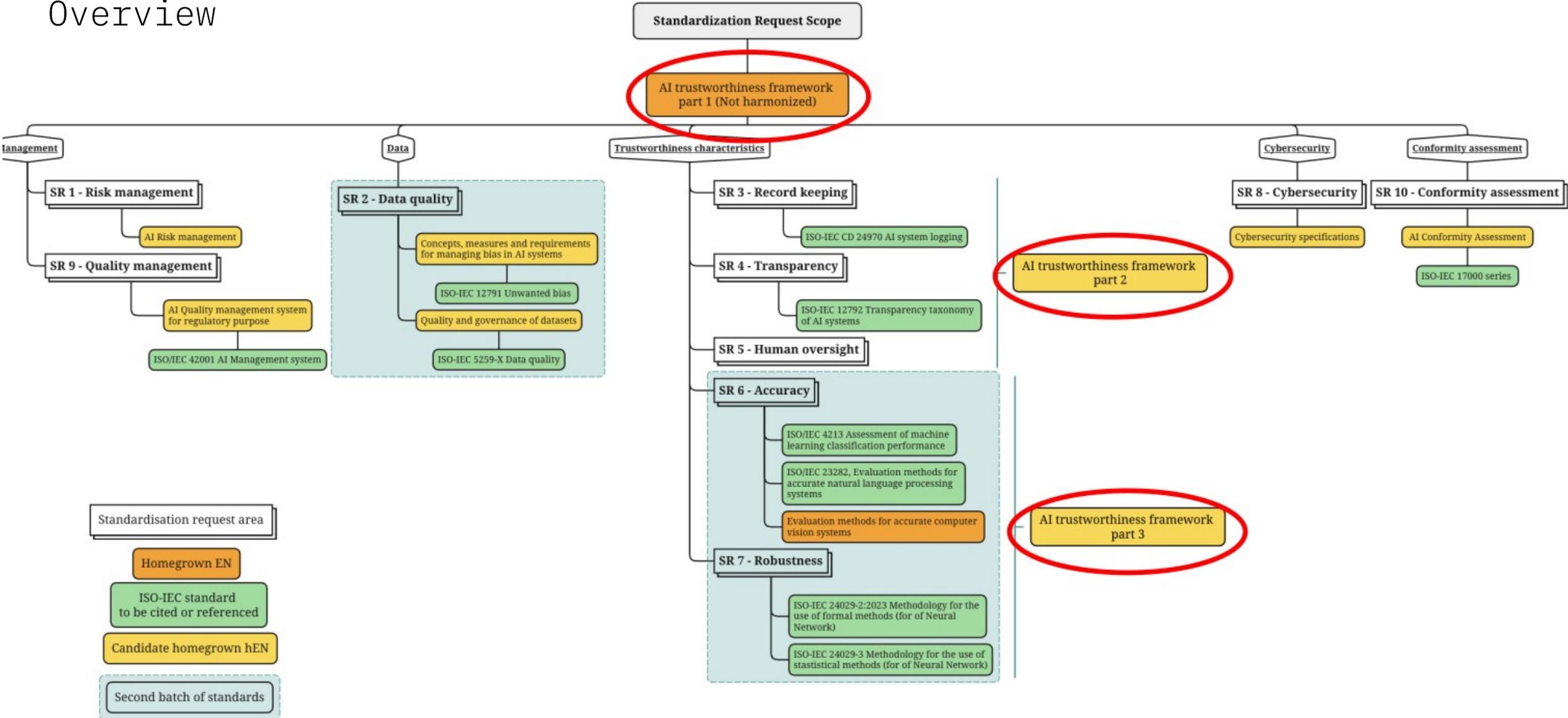
Accuracy, robustness and cybersecurity

Harmonised European Standards for AI

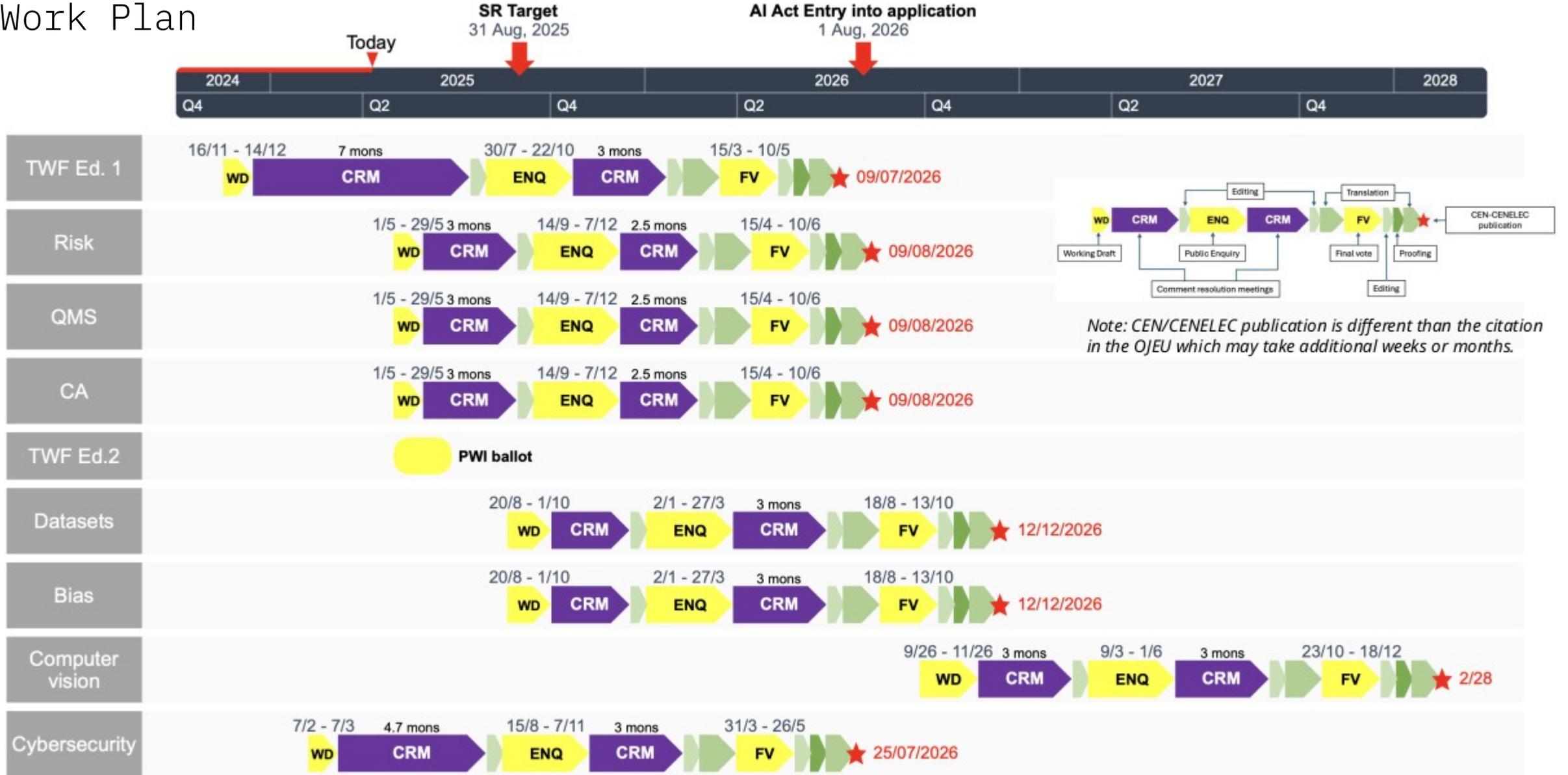
Standards intended to support the AI Act will be mapped on the following architecture of standards.



Standardisation Work – Overview



CEN-CENELEC Work Plan



Postcard: Cybersecurity for AI Systems

Standard(s) under development	Status and time plan	High level technical description
<p>JT021029</p>	<p>Status:</p> <p>WD</p> <p>Timeline:</p> <ul style="list-style-type: none"> ✓ CD Feb 2025 ✓ ENQ May 2025 ✓ FV Oct 2025 ✓ Publish: Feb 2026 	<ul style="list-style-type: none"> ✓ organizational and technical solutions aimed at ensuring the cybersecurity of high-risk AI systems over the life cycle ✓ The risk-based approach: risk assessment identifies AI cybersecurity risks. Risk treatment includes selecting controls to mitigate the identified risks ✓ Controls are structured in following <ul style="list-style-type: none"> • Main requirement • Rationale • Applicability • Exceptions to applicability • Sub-requirements • Recommendations • Risk reduction guidance.

Will the matter with the standards work out?

starting point

AI Act and harmonised standards for compliance – new territory. Initial slow progress, (too) many discussions, etc.

situation

Standardisation process needs time and means lot of effort.

Some standards may be late.

Many drafts are too complex and, in their current way, not implementable by industry.

Some rigour needs to be applied in the coming weeks to get things right.

risk

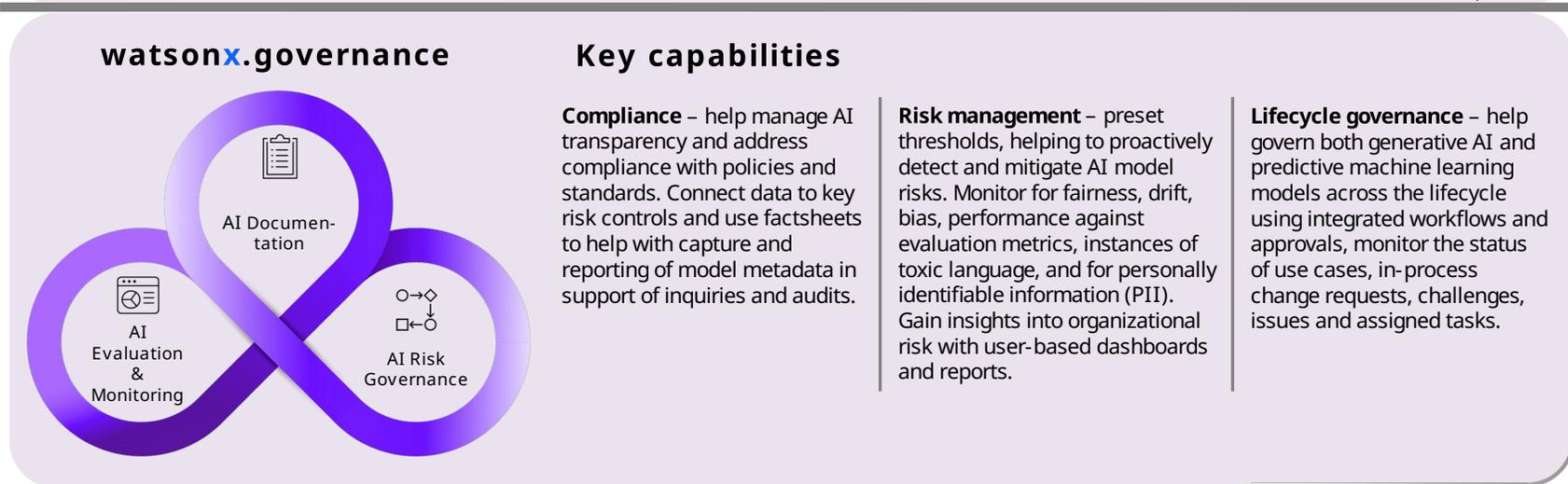
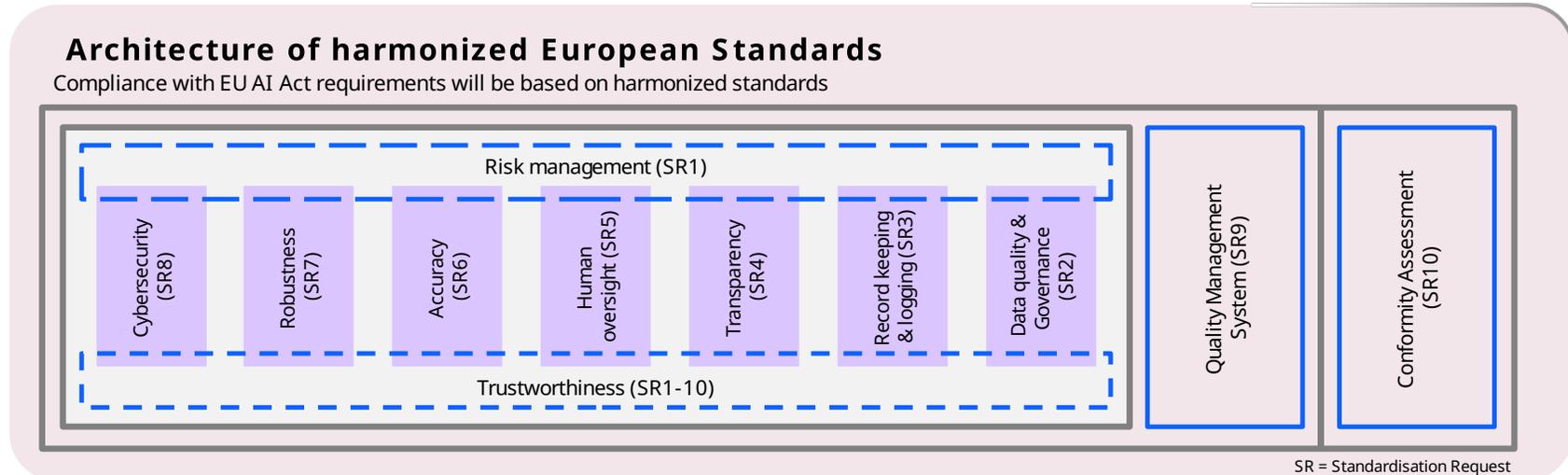
Standards may not be available in time or not listed in the Official Journal of the EU.

Market surveillance need to give some directions for this likely situation.

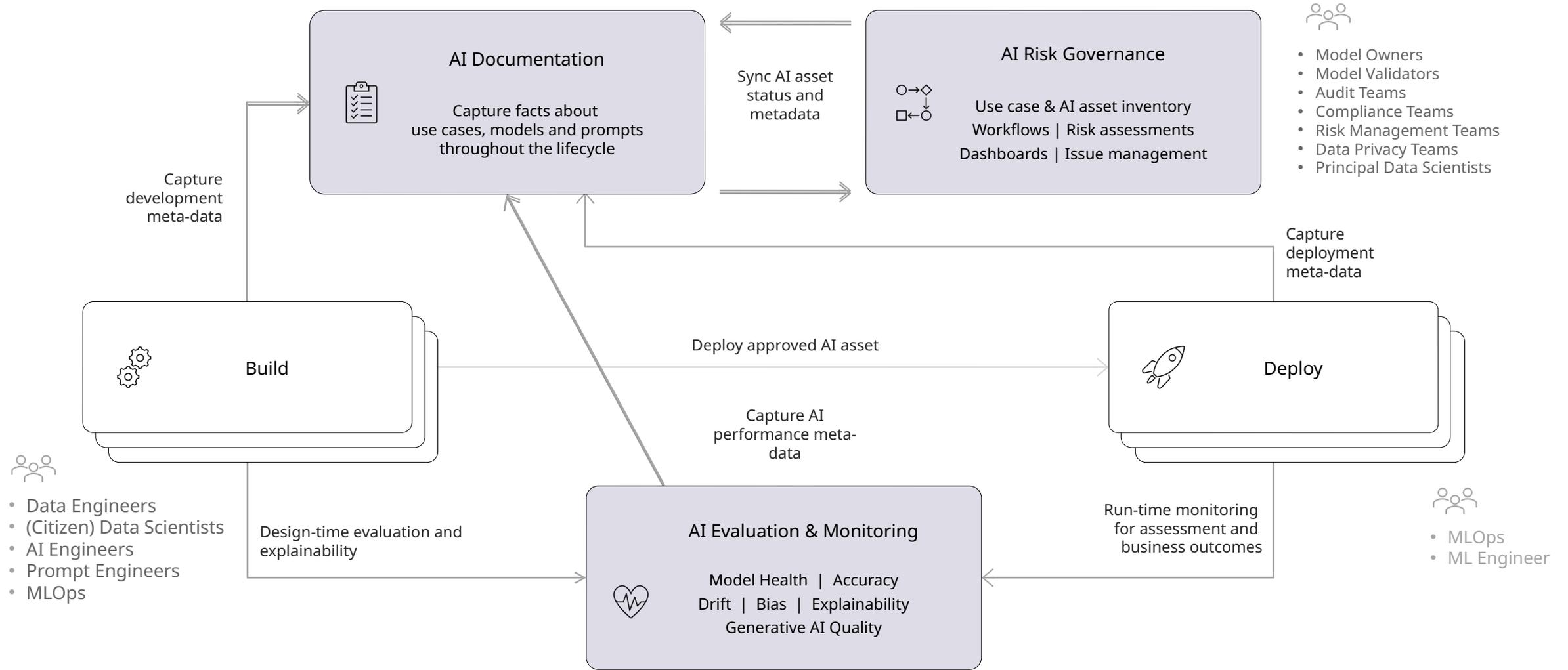
IBM governance tools aligned with European standards

IBM's watsonx.governance toolset is informed by the technical requirements laid down in the harmonised European standards under development.

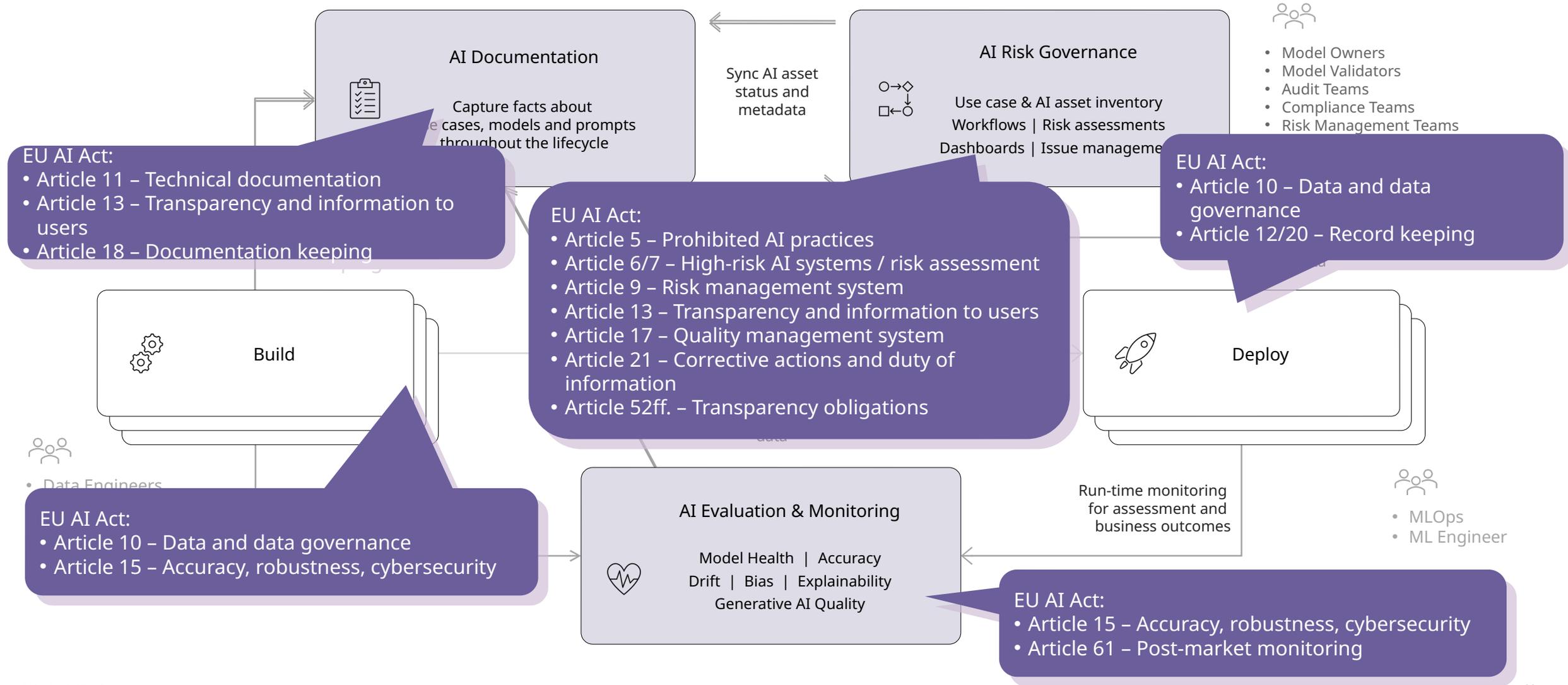
watsonx.governance enables performing the respective system management tasks, tests and lifecycle monitoring, inter alia by providing comprehensive dashboards.



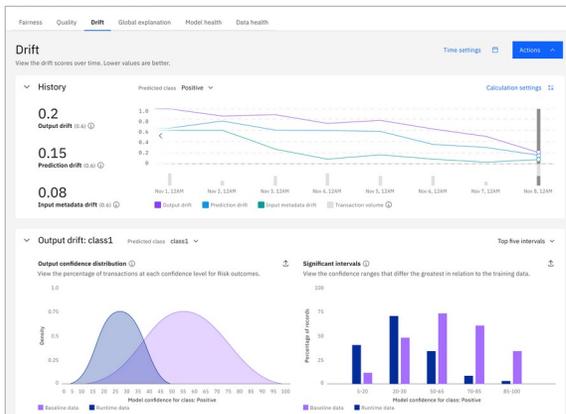
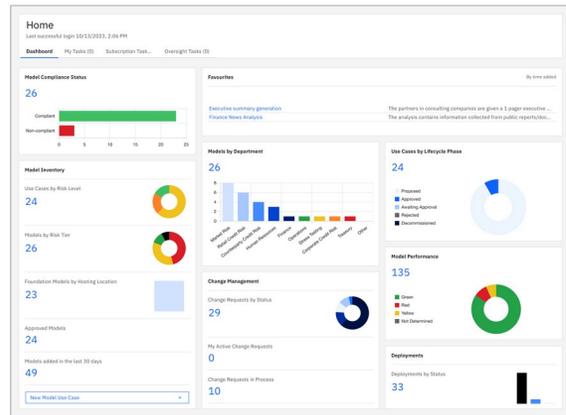
watsonx.governance - conceptual mapping of potentially relevant provisions of the EU AI Act



watsonx.governance - conceptual mapping of potentially relevant provisions of the EU AI Act



watsonx.governance support for compliance with the EU AI Act



Applicability and Risk Categorisations

[Articles 5,6,7]

Watsonx.governance provides EU AI Applicability and Risk Categorisation Assessment Questionnaire. Updates on the act will be considered via regularly provided updates on these questionnaires.

□ Governance Console



Compliance Requirements for High-Risk AI Systems

[Article 8]

watsonx.governance is a compliance tracking system that monitors and ensures adherence to the EU AI Act and other relevant regulations including a unified documentation and reporting system

□ Governance Console, AI Documentation



Risk management system for high-risk AI systems

[Article 9]

watsonx.governance is a comprehensive risk management system for AI systems, identifying, analyzing, estimating, and evaluating risks, as well as adopting appropriate risk management measures.

□ Governance Console



Need for high-quality data sets and robust data governance practices

[Article 10]

Part of the development process identify bias in training data etc.

□ Evaluation & Monitoring



Technical documentation

[Article 11]

Workflows in the Governance console ensure the documentation is in place before a model is put into production. All metadata of a model and its development and monitoring activities are automatically captured in the AI factsheet.

□ Governance Console, AI Documentation



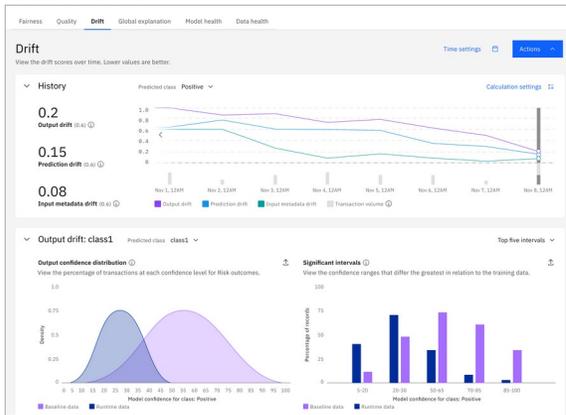
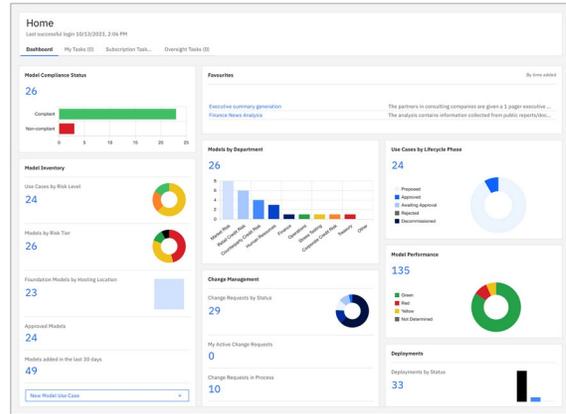
Record-keeping

[Article 12, 20]

Model inferences are logged through the Monitoring service, regardless of the deployment environment, in order to record risk-related events and increase transparency

□ Evaluation & Monitoring

watsonx.governance support for compliance with the EU AI Act



Transparency and Provision of Information to Deployers of High-Risk AI Systems [Article 13]

Model cards (watsonx.ai)



Human Oversight of High-Risk AI Systems [Article 14]

watsonx.governance allows effective oversight by humans during their use of high-risk systems

□ Governance Console



Accuracy, robustness and cybersecurity [Article 15]

Monitor for various accuracy metrics through the model lifecycle, preventing drift and bias

□ Evaluation & Monitoring



Documentation keeping [Article 18]

AI factsheets remain in the system through the lifecycle of a use case and can be exported as PDF documents to be stored in dedicated folders / archives

□ AI Documentation

Intermediate Summarising Remarks

Deep involvement and high investment of IBM into European and international standardisation bringing in our experience on trustworthy AI.

IBM has decade-long experience with the EU regulatory system, the New Legislative Framework and the use of harmonised European standards for compliance.

Standards required for compliance with the AI Act are under way with a clear work and time plan.

It must be expected that some standards or their citation on the OJEU will be late – market surveillance authorities should provide guidance and solutions for this case.

IBM has knowledge of evolving AI standards and is able to provide optimal support to clients on this basis.

IBM's tools are informed by the requirements laid down in the AI Act and the standards for supporting good governance of AI systems.

ISO 42001 – Not for compliance with the EU AI Act

ISO 42001 is a “Management System Standard” intended for certification (similar to ISO 9001 or ISO 27001).

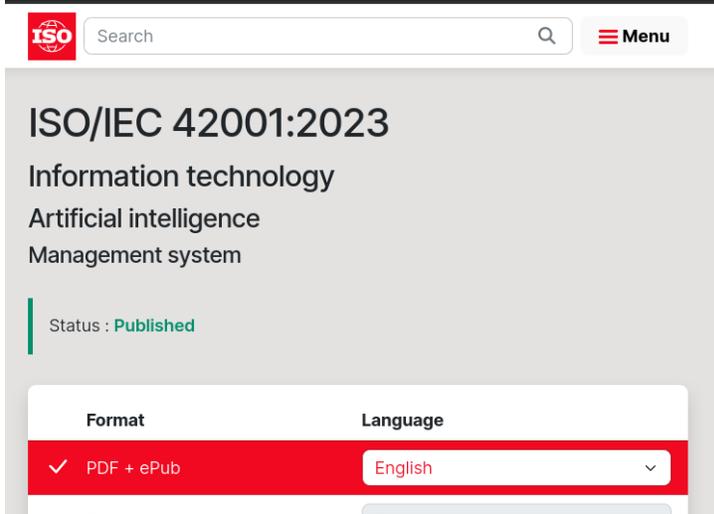
It sets certain controls around trustworthiness, governance and responsible AI that an organisation should fulfil – but not specific for high-risk AI systems.

The European Commission made very clear that ISO 42001 is not suitable for meeting the requirements of the EU AI Act:

“[42001’s] primary objective is to help organisations manage uncertainty in line with their own organisational and business goals, rather than to ensure a high level of protection for health, safety, and fundamental rights as required by AI Act.

“While recognising the differences between medical devices and the AI systems, EN ISO 13485 offers a regulatory logic, conceptual framework and structure that is more closely aligned to new legislative framework and the AI Act (e.g. on the definition of risk, and safety objectives) than ISO/IEC 42001.”

[From a recent submission of the European Commission to CEN-CENELEC JTC 21.]



The screenshot shows the ISO website interface for ISO/IEC 42001:2023. At the top, there is a search bar and a menu icon. The main content area displays the standard title "ISO/IEC 42001:2023" in a large font, followed by the categories "Information technology", "Artificial intelligence", and "Management system". Below this, the status is indicated as "Published". At the bottom of the screenshot, there are two dropdown menus: "Format" with "PDF + ePub" selected and "Language" with "English" selected.

Many thanks for your attention...

... handing over to Monica

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<https://www.linkedin.com/in/jochenfriedrich/>