

# Design of a Quality Management System Based on the EU AI Act

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# Design of a QMS Based on the EU AIA



## Motivation - Problem Statement

### Problems of the EU AIA - Comments by legal experts:

- AIA lacks specificity for several (technical) requirements (e.g., Art. 9, Art. 15, etc.) [1].
- AIA imposes high bureaucratic demands and requires substantial resources to demonstrate compliance, especially for high-risk AI systems [1,2].

### A survey of existing AI audit frameworks and tools has shown [3]:

- *Problems*: Lack of stakeholder inclusion, poor communication, and the absence of standardized designs.
- *Solutions*: Enhancing AI audit accountability by developing standardized, open-source frameworks and tools.

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[1] Bormhard/ Siglmüller. AI Act – das Trilogergebnis. Recht Digital - RD. 2024;2:45-96.

[2] Schallbruch M. EU-Regulierung der Künstlichen Intelligenz: Informationstechnische Systeme im Fokus neuer rechtlicher Anforderungen. Datenschutz und Datensicherheit - DuD. 2021;45:438-43.

[3] V. Ojewale, R. Steed, B. Vecchione, A. Birhane, and I. D. Raji, "Towards AI accountability infrastructure: Gaps and opportunities in AI audit tooling," CoRR, 2024. doi: 10.48550/.

# Design of a QMS Based on the EU AIA

## Motivation - Problem Statement



### Example: Available open-source QMS-tool from research - careAI

**AITI. CareAI: Responsible AI Index**

Responsible AI Index  
Developed in cooperation with European Commission's High-Level Expert Group on AI.

Responsible AI Wizard [Demo Mode] | HA & HO | TR & S | P & DG | Transparency | DN & F | E & SW | Accountability | Responsible AI Index

**Human Agency & Human Oversight**

**Human Agency**

Human Oversight

Fundamental Rights

Results

Analysis & Visualization

Note: Please answer all the questions carefully. Some questions can be answered on a scale of 1 to 4, where 1 indicates "low priority" or "to a lower extent", and 4 indicates "high priority" or "to a higher extent".  
 If the question does not apply to your context, please mark 0 indicating "not applicable (N/A)".

1. Is the AI system designed to interact, guide or take decisions by human end-users that affect humans and/or society?

Yes  No

2. Could the AI system generate confusion for some or all end-users or subjects on whether a decision, content, advice or outcome is the result of an algorithmic decision?

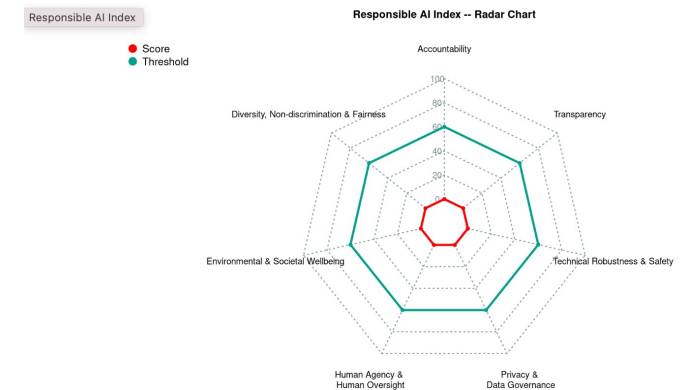
N/A  1  2  3  4

3. Are end-users or other subjects adequately made aware that a decision, content, advice or outcome is the result of an algorithmic decision?

Yes  No

4. Could the AI system affect human autonomy by generating over-reliance by end-users?

N/A  1  2  3  4



[3] E. Thelisson, and H. Verma, „Conformity assessment under the EU AI act general approach,“ AI and Ethics, 2024. 4(1): p. 113-121.

[4] ATI, careAI website: <https://aitransparencyinstitute.com>, accessed on 11 December 2024

Risk Criteria	Score	Required	Strength
Accountability	0.00	60.00	NA
Diversity, Non-discrimination & Fairness	0.00	60.00	NA
Environmental & Societal Wellbeing	0.00	60.00	NA
Human Agency & Human Oversight	0.00	60.00	NA
Privacy & Data Governance	0.00	60.00	NA
Technical Robustness & Safety	0.00	60.00	NA
Transparency	0.00	60.00	NA

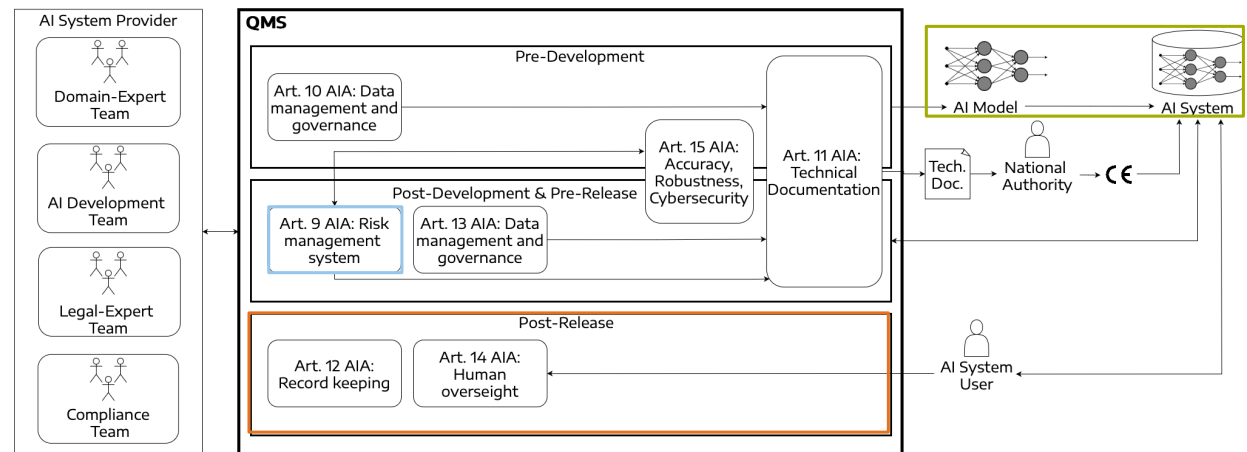
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# Design of a QMS Based on the EU AIA

## Motivation – Approach & Goal

Idea: **Automated internal and external AI compliance checks by:**

1. ... having a **QMS application** containing several sub-services, each for one or multiple AIA requirements.
2. ... connecting to the **AI System (Model)** for technical assessments.
3. ... adopting to a **workflow engine** for permanent logging post-release.



**Goal:** A single tool to map, perform, and track the compliance management process for AI systems.

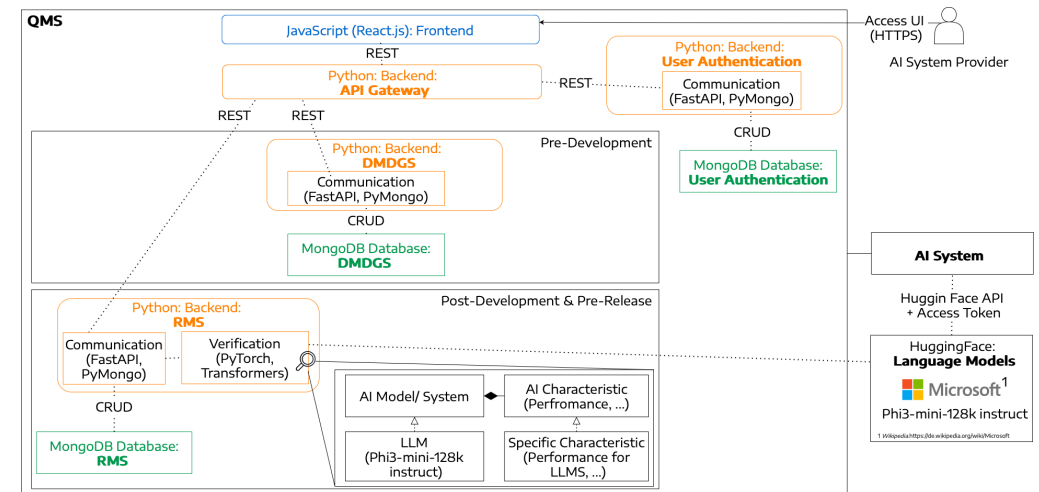
# Design of a QMS Based on the EU AI Act



## Prototype - Design & Architecture

### Design and Architecture:

- Microservice-based design.
- Connection to LLM: Phi3-mini-128k-instruct.
- Strategy Software Design Pattern for the efficient implementation of technical assessment metric for AI model assessments.



### Prototype:

- Check the web-based application (<https://power.bpm.cit.tum.de/qmsAIA/>)



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## Evaluation – Qualitative Analysis

### **Workshop with IT experts and Interview with legal expert:**

- Focus group discussion with 7 IT experts.
- Expert interview with 1 legal expert.

**Question of interest:** *Does the proposed QMS improve efficiency of the AI compliance management process and reduce the required resources?*

 6 (5 IT & Legal) experts totally agreed on that, 2 (IT) experts had no opinion.

### **Further Recommendation by Experts:**

- Evaluate which tasks cannot be automatically checked within the QMS.
- The QMS should be broad enough to accommodate and document all types of AI systems.

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## Limitations

- **Only two basic sub-services have been implemented** so far: Article 9 (Risk Management System) and Article 10 (Data Management and Governance System).  
➡ *More comprehensive sub-services need to be designed and implemented.*
- **Only one LLM** (Phi3-mini-128k-instruct) is **connected to the QMS prototype**.  
➡ *The QMS must be able to connect to additional and diverse types of AI models and systems.*
- **Only 8 experts were consulted**, which led to limited results from the evaluation.  
➡ *Expand evaluation in future work. Conduct more interviews for the requirement elicitation process, and evaluation to provide comprehensive and significant results.*

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## Future Work

One example for future work: **A generalized EU AIA sub-service design process**

1. Define **list of sub-services**.

2. Use existing methodologies (from research) to establish a **list of requirements** (from EU AIA, ISO standards, etc.) **for each sub-service**.

3. Create a **process model** and annotate it with the required data **for each requirement list**.

4. Implement **each process and data model** and incorporate humans in the execution (e.g., using a workflow engine).

5. Use **logs generated by the workflow engine** to ensure transparency and optimize sub-services using process mining techniques **for each implemented process**.



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Thank you for attending the presentation!

Any questions? 😊

