Harmonized Documentation Guidelines for Trustworthy AI Systems

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Driving Trustworthy AI through Design and Regulation

27 January 2026, Nicosia

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2. Being an enabler of Standards
3. Being Global
4. Being Versatile
5. Being Inclusive

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from more than 60 countries

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engaged in more than 4000 meetings

58 000+ standards
published in total

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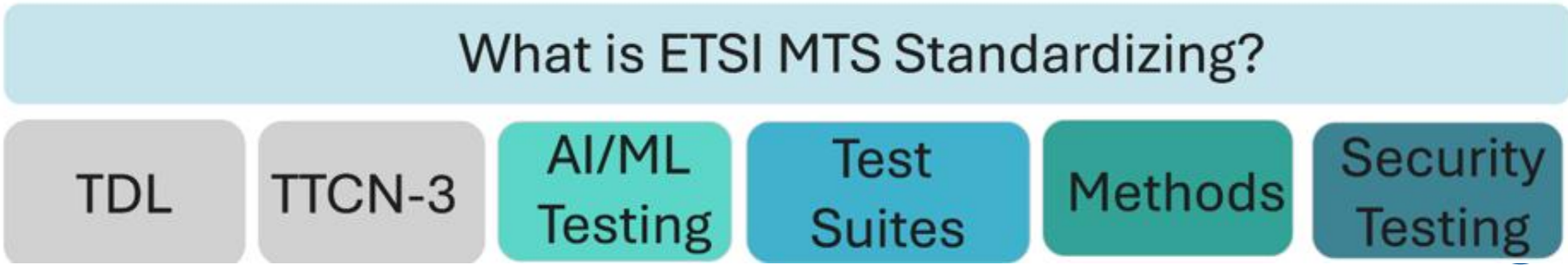
https://www.etsi.org/e-brochure/Strategy/Strategy%20Leaflet/mobile/index.html

Who is ETSI TC MTS?

Technical Committee Methods for Testing and Specification

- Creates testing guidelines, frameworks, notations, and methodologies independent of application domains
- Goals
  - High-quality Standards
  - Efficient Testing
- Working groups
  - **TST** – Test & Specification Techniques
  - **AI** – AI Testing

https://www.etsi.org/committee/mts



The Trust Deficit in AI

Why Trust Matters & The Strategy of ETSI TC MTS AI

Trust and Trustworthiness

Terms

Trust (by someone)

- in a person's mind, differs by individuals or varies over time
- is subjective

Trustworthiness (of something)

- mixture of many measurable characteristics
- more objective

Documentation of trustworthiness characteristics to increase trust

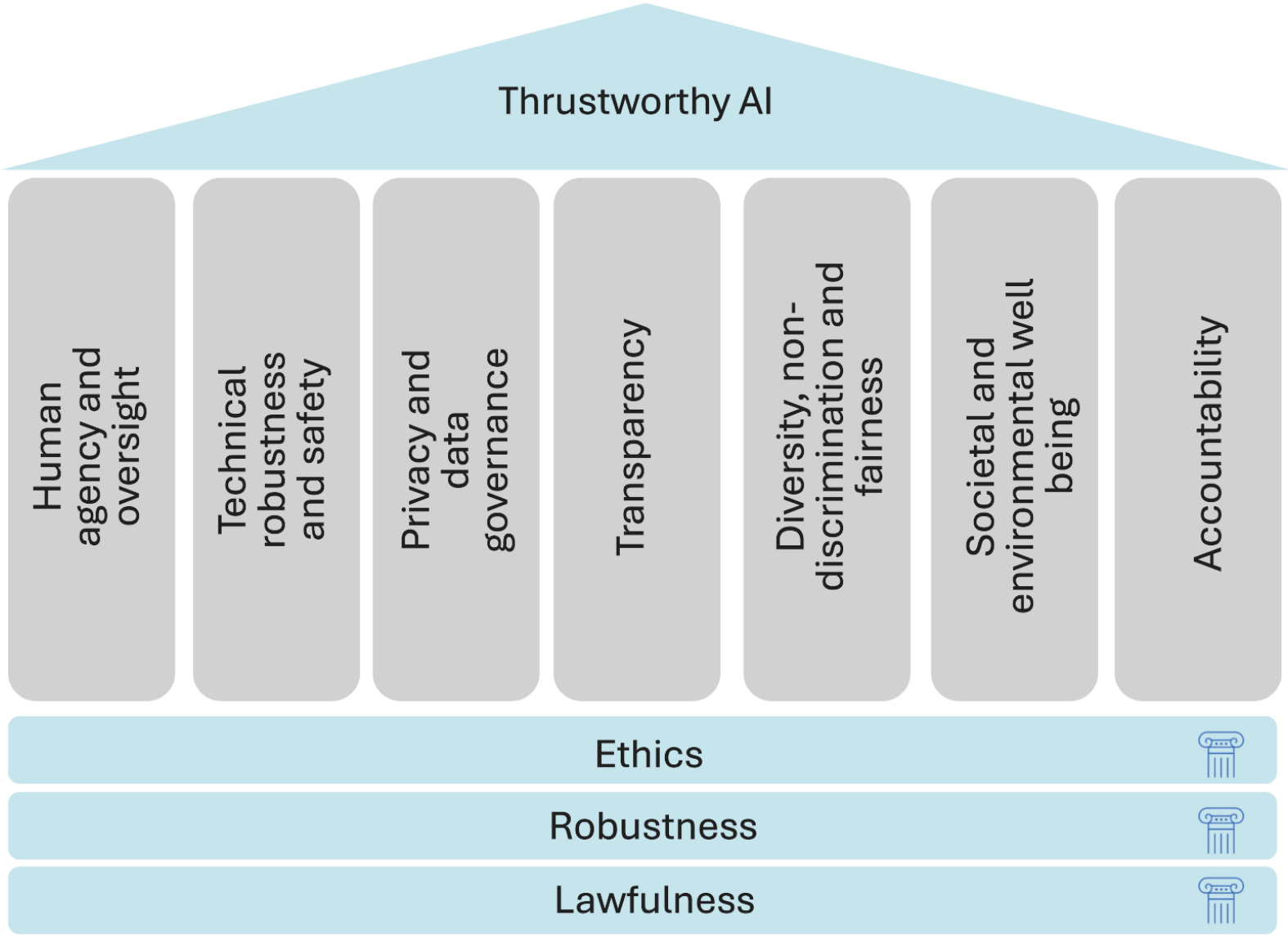
Defining Trustworthiness in AI

Trustworthy AI is built on three core pillars

- Ethics
- Robustness
- Lawfulness

https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

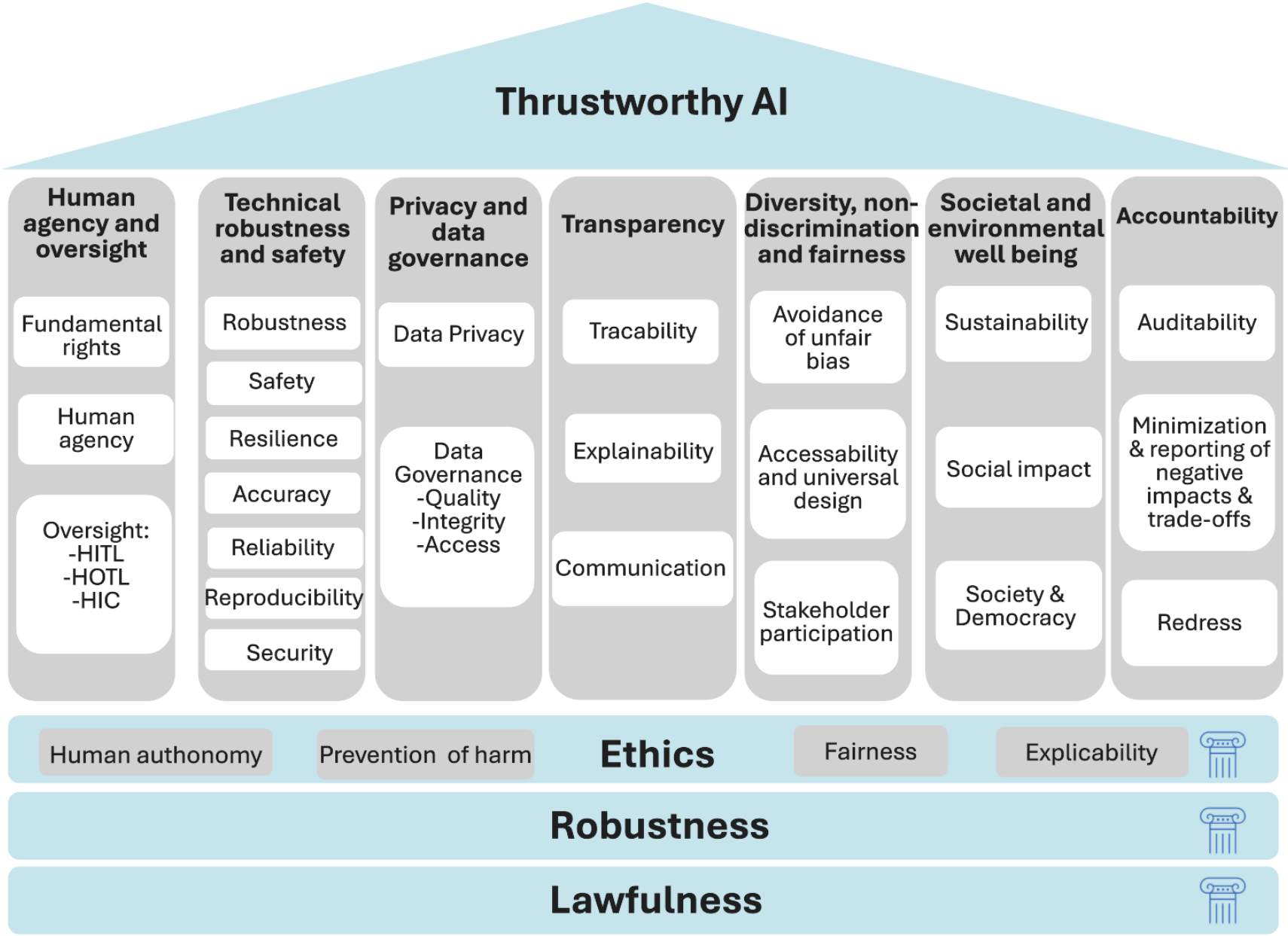
Defining Trustworthiness in AI



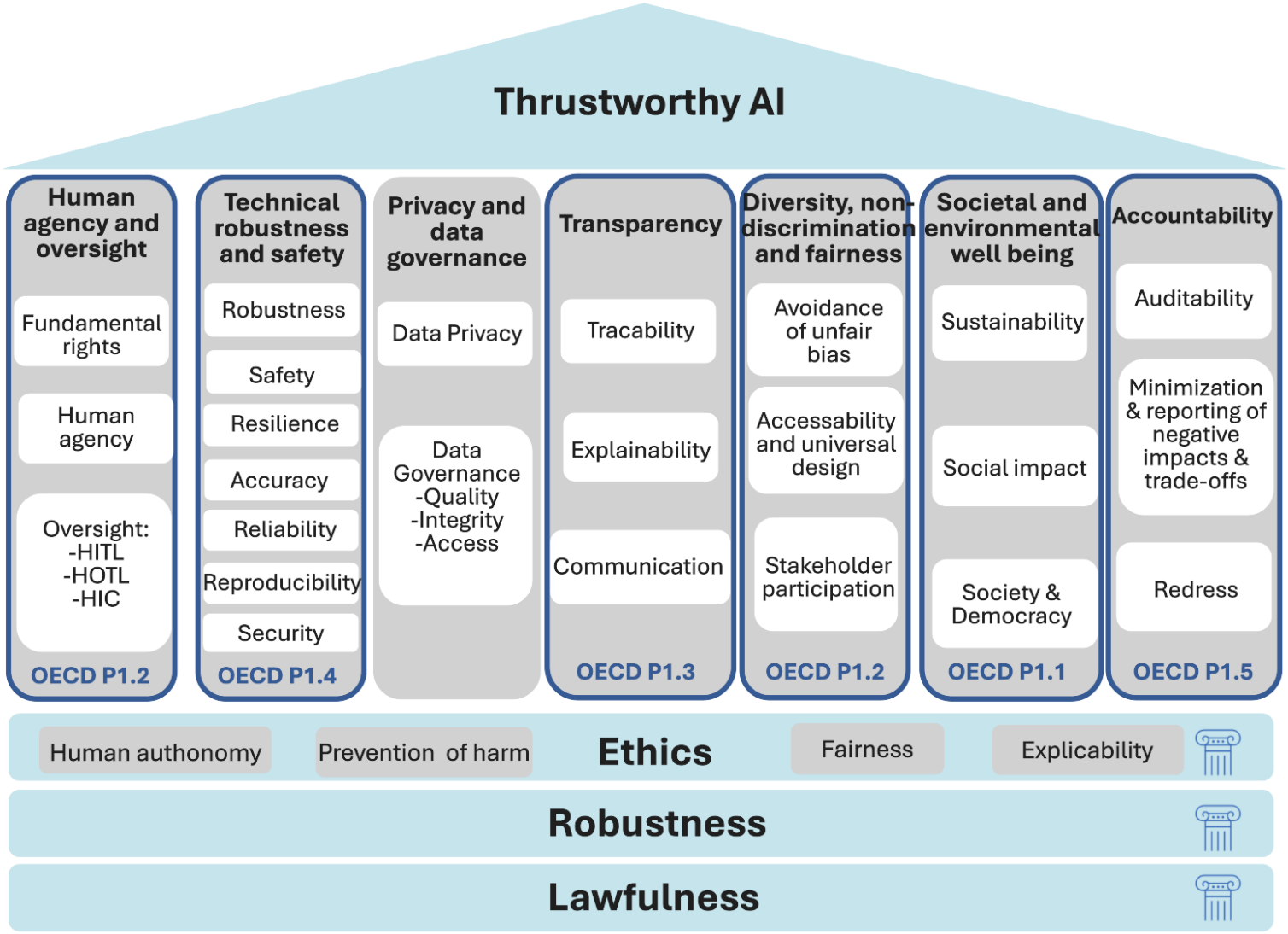
https://altai.insight-centre.org/

https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

Defining Trustworthiness in AI



Key OECD Principles for AI Trustworthiness



OECD.AI Policy Observatory

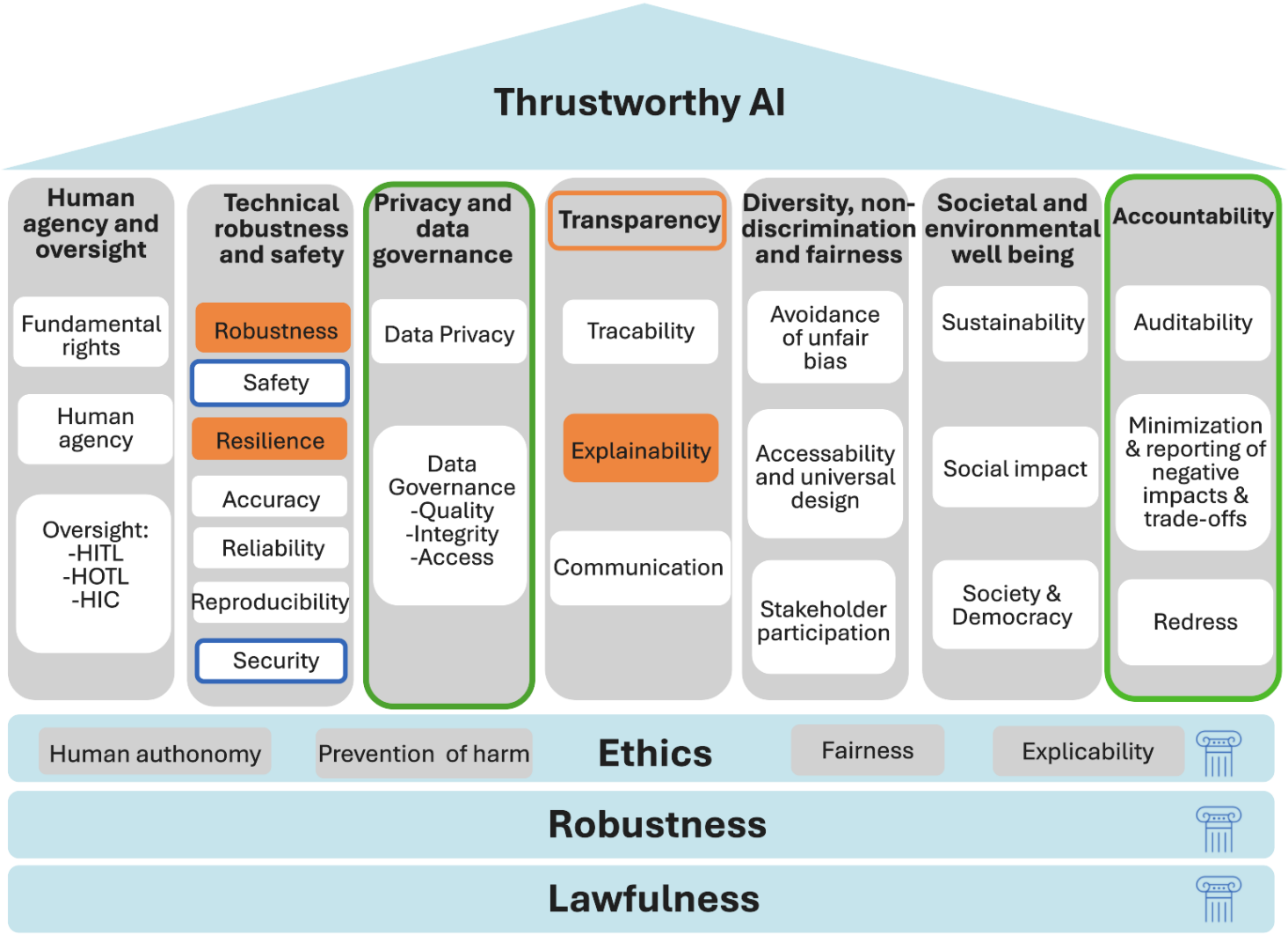
OECD Principles

- **P1.1** Inclusive growth, sustainable development and well-being
- **P1.2** Human-centered values and fairness
- **P1.3** Transparency and Explainability
- **P1.4** Robustness, Security, and Safety
- **P1.5** Accountability

https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449

https://www.oecd.org/en/about/programmes/global-partnership-on-artificial-intelligence.html

ISO/IEC TR 24028:2020 Overview of trustworthiness in AI



High-Level Concerns

- **HLC 1** Responsibility, Accountability, and Governance
- **HLC 2** Safety

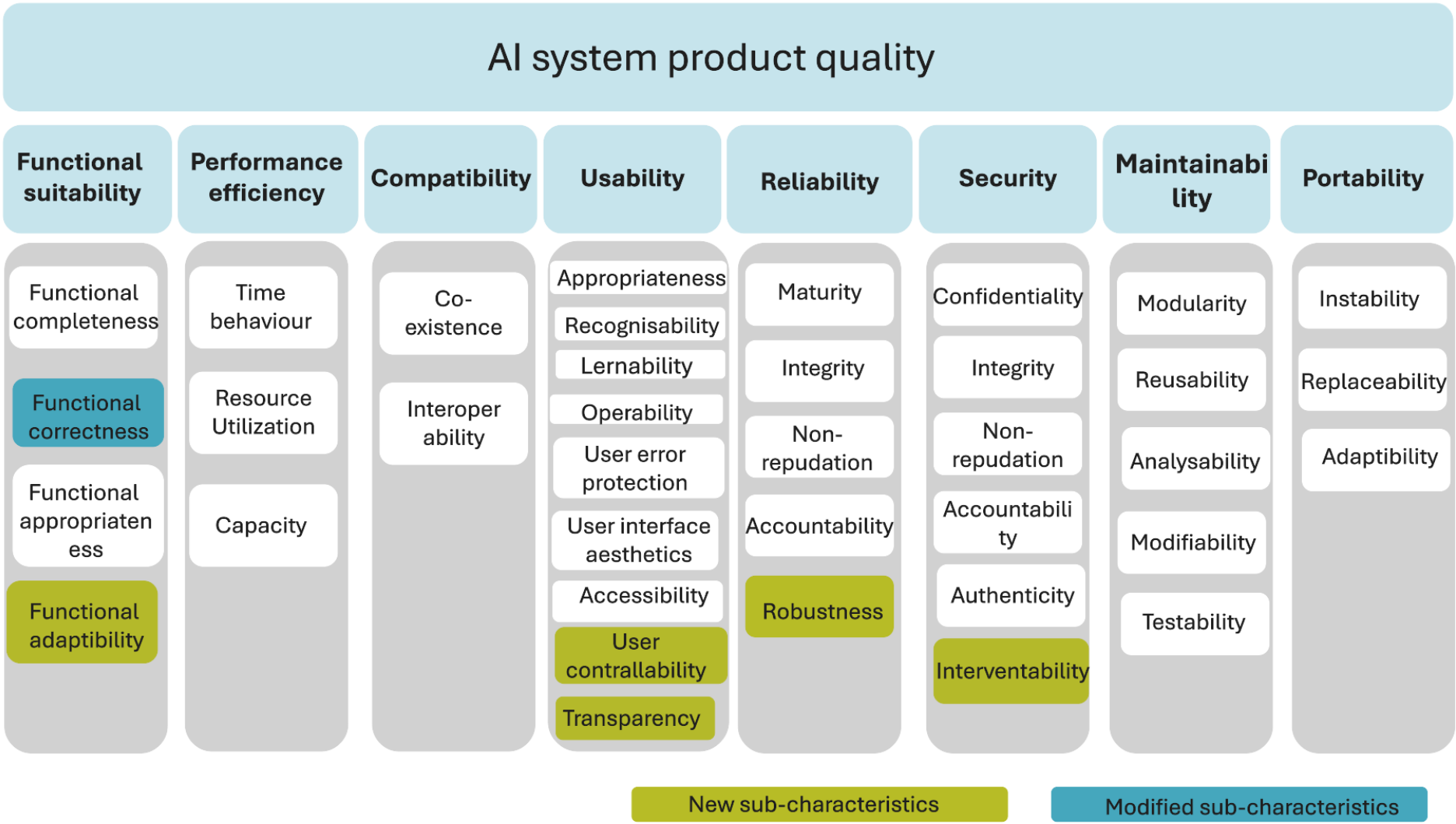
- **HLC 3** Vulnerabilities, Threats, and Challenges

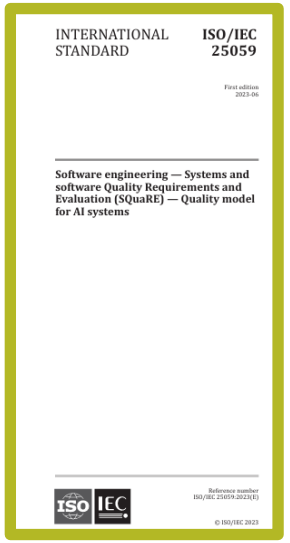
Mitigation measures

- Robustness, Resilience, Transparency, Explainability

https://www.iso.org/standard/77608.html

Quality model for AI systems





ISO/IEC 25059:2023 (E)

Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI systems

https://www.iso.org/standard/80655.html

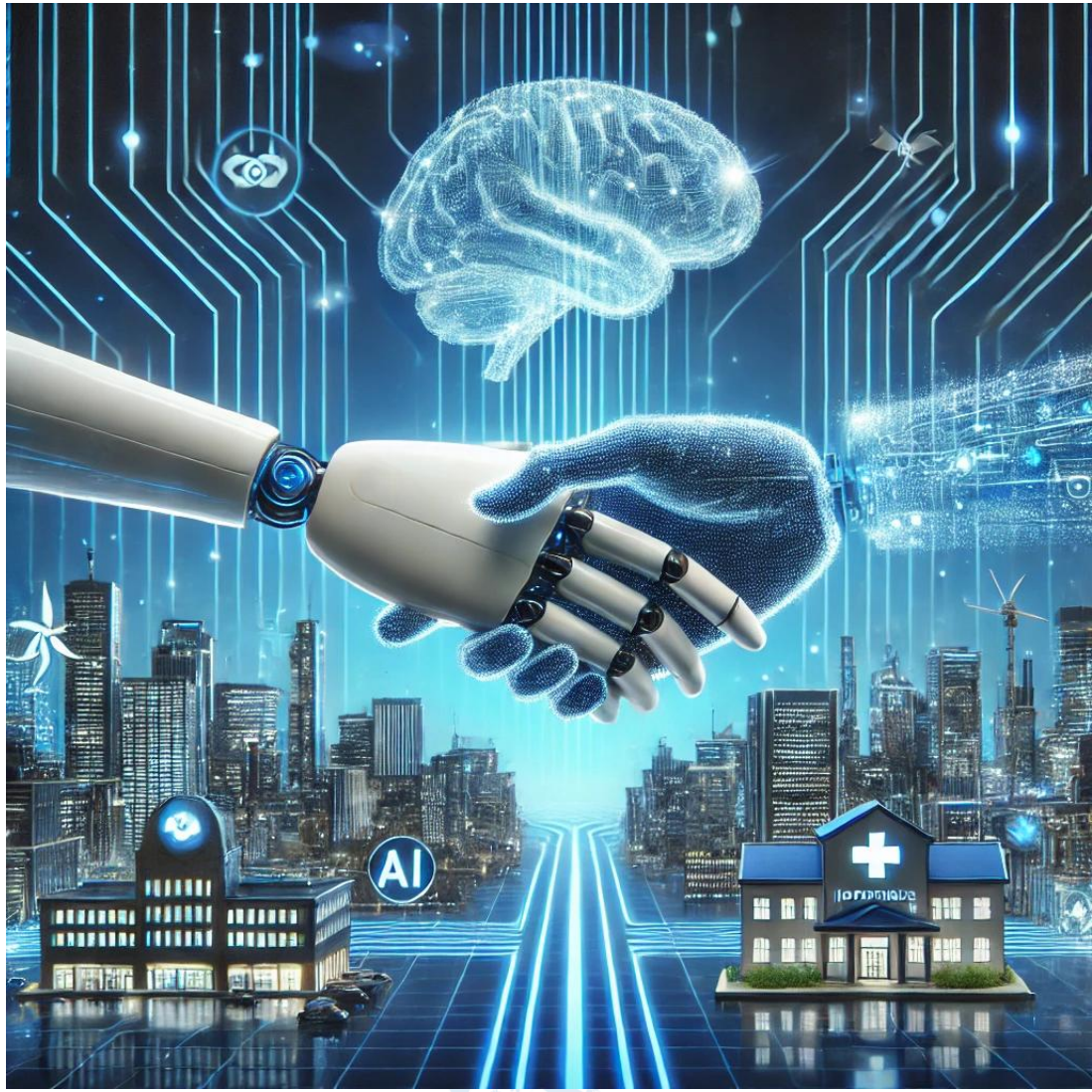
Bridging the AI Trust Gap

Challenges in ensuring AI Trustworthiness

- Depends on multiple requirements, capabilities and qualities, which vary by context
- No single approach guarantees trust
- Current standards provide high-level guidance

How Can We Build Trust?

- Testing and Validation
- Regulatory Compliance
- Transparent Documentation



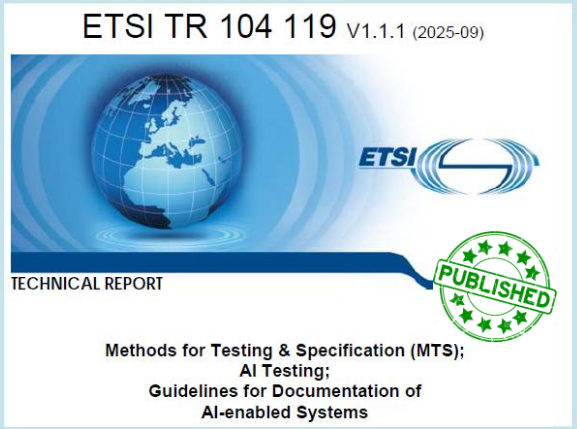
Source: OpenAI. (2025). [AI-generated image]. DALL·E.

ETSI TC MTS AI Strategy: Foster trust in AI-enabled systems

Test Methodology and Test Specification for ML-based Systems

Continuous Auditing-Based Conformity Assessment for AI-enabled systems

Guidelines for documentation of AI-enabled systems



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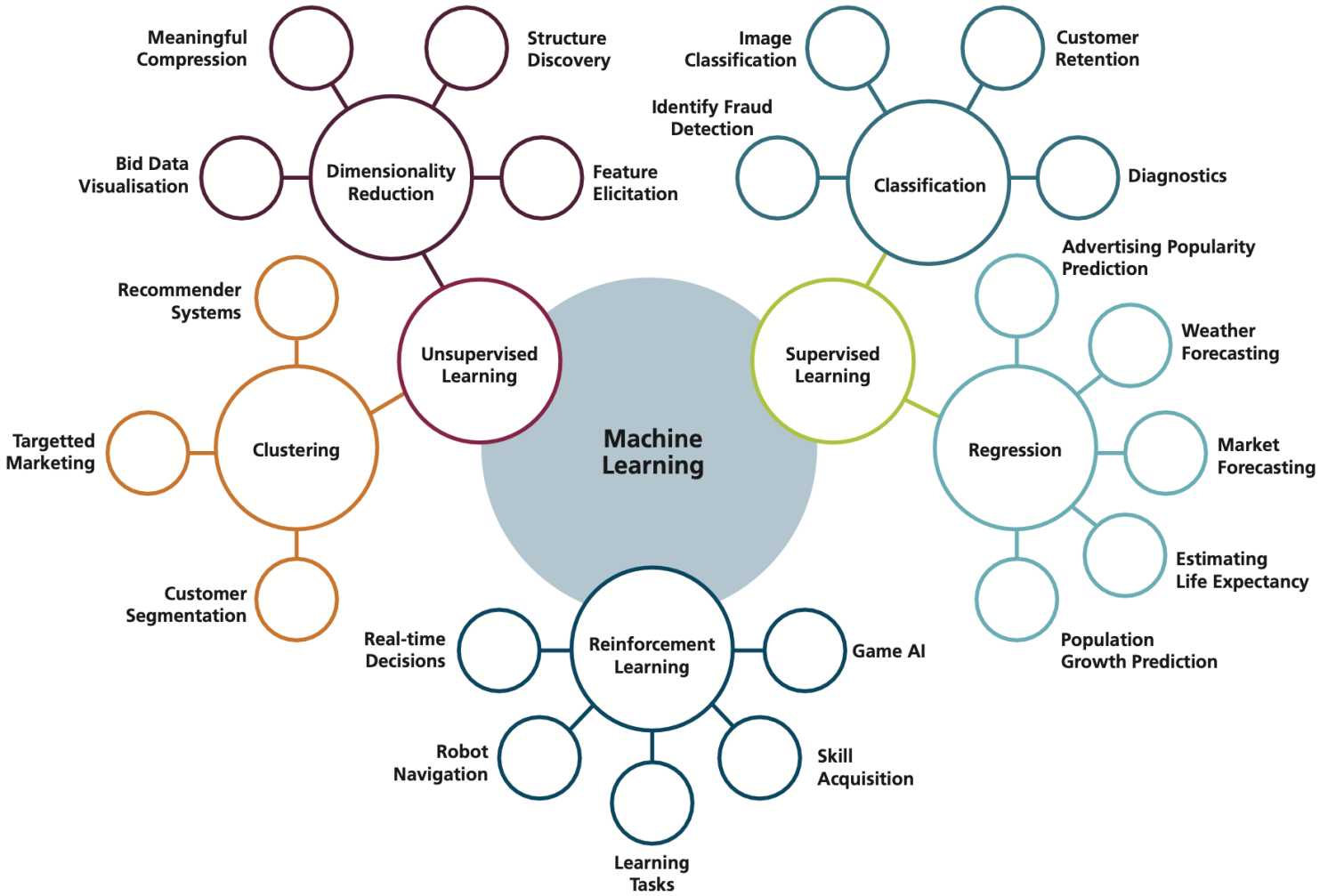
ASSESSING AI RISK

TR 103 910: Challenges and specifics of testing ML systems

- ML adoption in critical applications
- Need for rigorous testing
- Diverse application domains
- Open context
- Diverse technologies and approaches



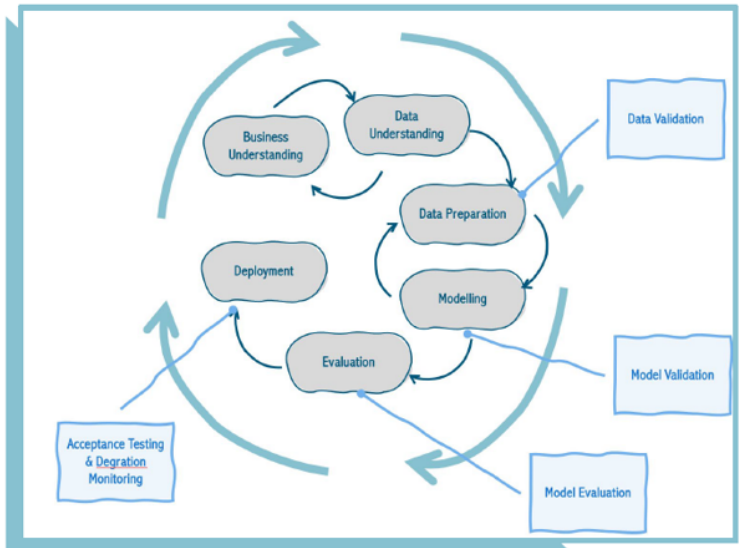
Scope of TR 103 910

- Covers testing methodologies for ML-based systems
- Quality criteria and lifecycle integration
- Relevant for developers, QA engineers, regulators

- **Model relevance** (does it fit the task?)
- **Correctness** (accuracy, precision, recall)
- **Robustness** (handling noise & adversarial inputs)
- **Bias avoidance** (fair decision making)
- **Security** (protection against vulnerabilities)
- **Explainability** (making ML decisions understandable)

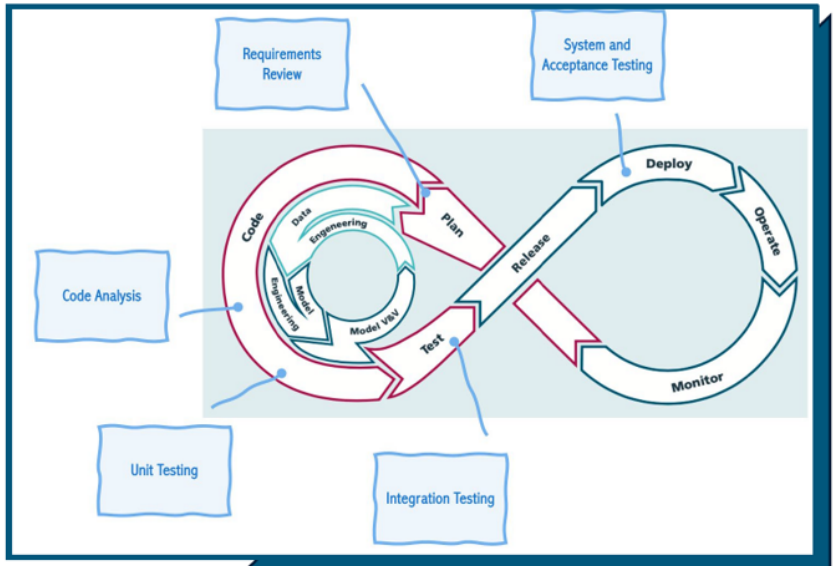
Contents

TR 103 910: Integrates data science and software engineering



Data Science

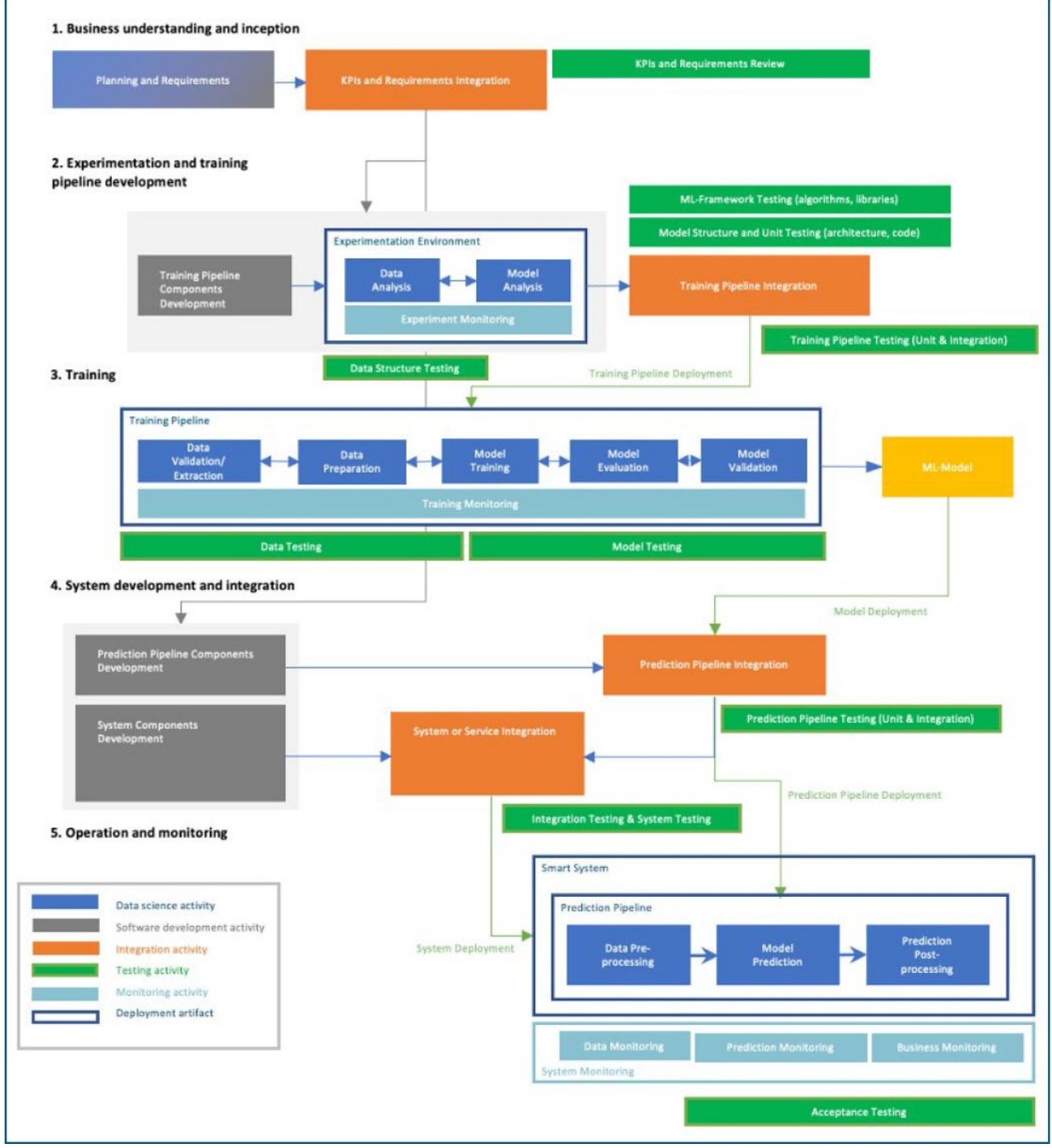
- Terminology from data science, software engineering, IT-operations, statistics …
- Considers differences in strategies e.g. from optimization and construction
- Addresses MLOps software infrastructures



Software Engineering

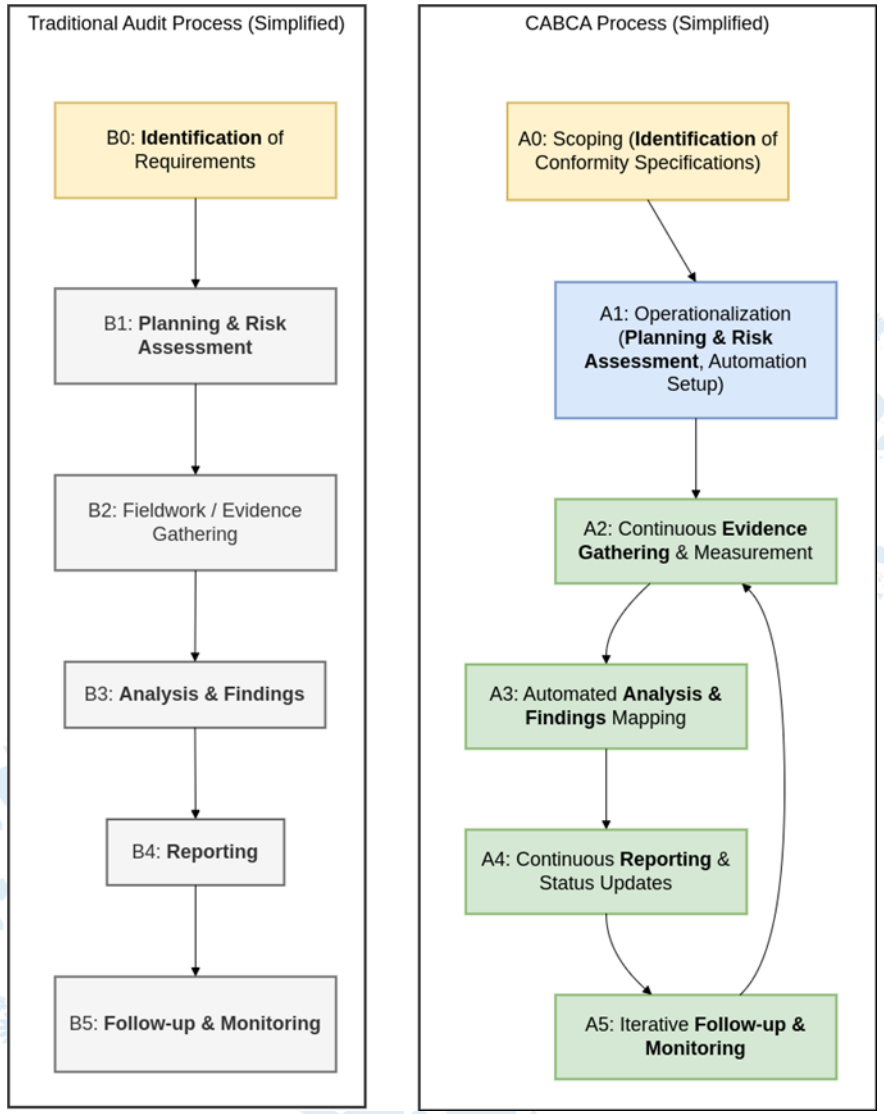
TR 103 910: Common Life Cycle Model

- **Phases**
  1. Business understanding and inception
  2. Experimentation and training pipeline development
  3. Training
  4. System Development and Integration
  5. Operation and monitoring
- **Distinguishes**
  - Data Science Activities
  - Software Development Activities
  - Integration Activities
  - Testing & Monitoring Activities



TS 104 008: Continuous Auditing-Based Conformity Assessment

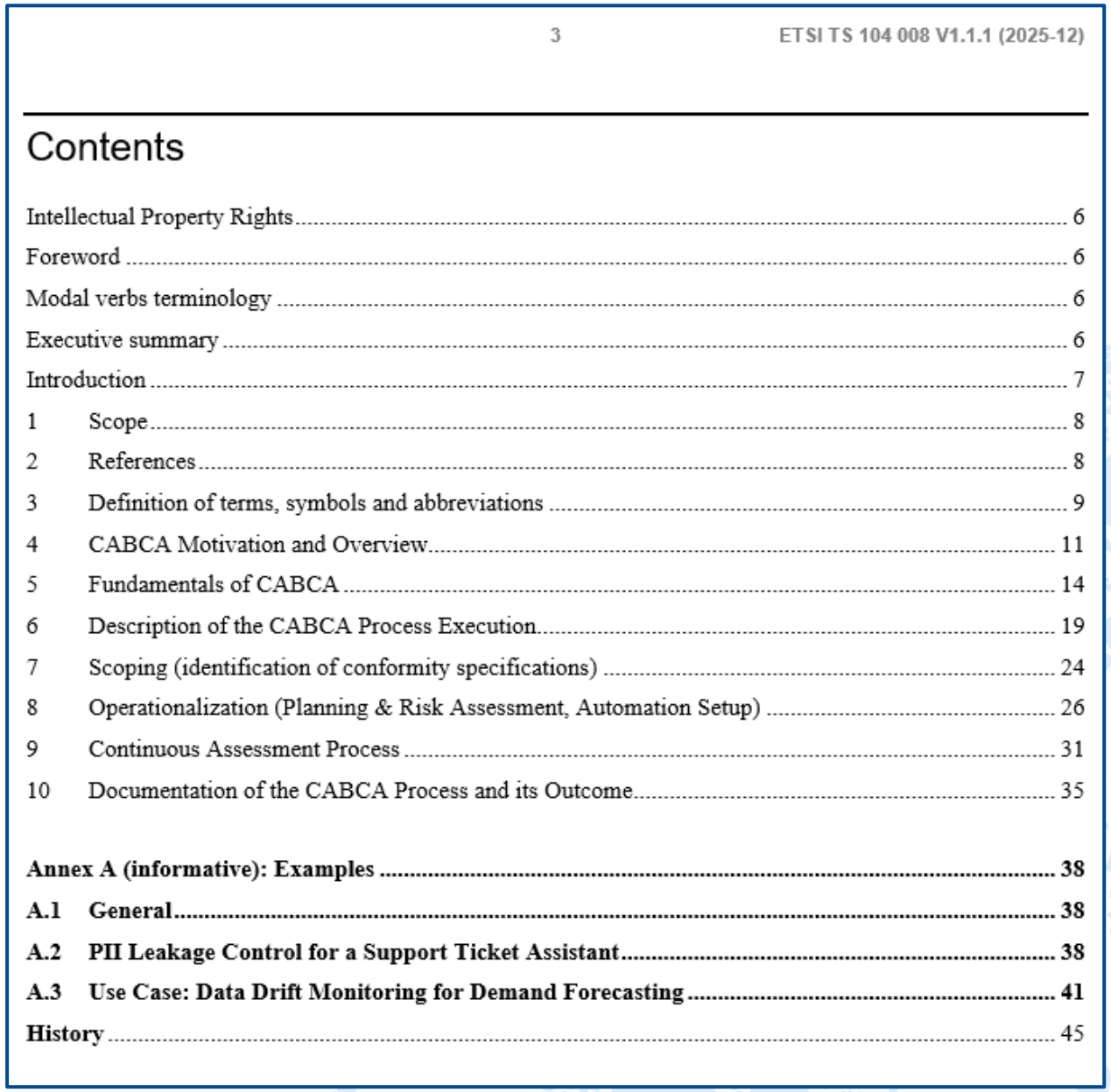
- ETSI TS 104 008: Continuous Auditing-Based Conformity Assessment for AI-enabled systems
- Enables automatic + continuous tracking of regulatory requirements
- Translates EU AI Act/standards into measurable compliance criteria
- Continuous monitoring of evidence across the AI lifecycle
- Supports self-assessment, third-party assessment, certification
- Shift from one-off audits → iterative, ongoing compliance



Source: ETSI DTS/MTS-104008 “Continuous Auditing-Based Conformity Assessment for AI-enabled systems (**CABCA**)”

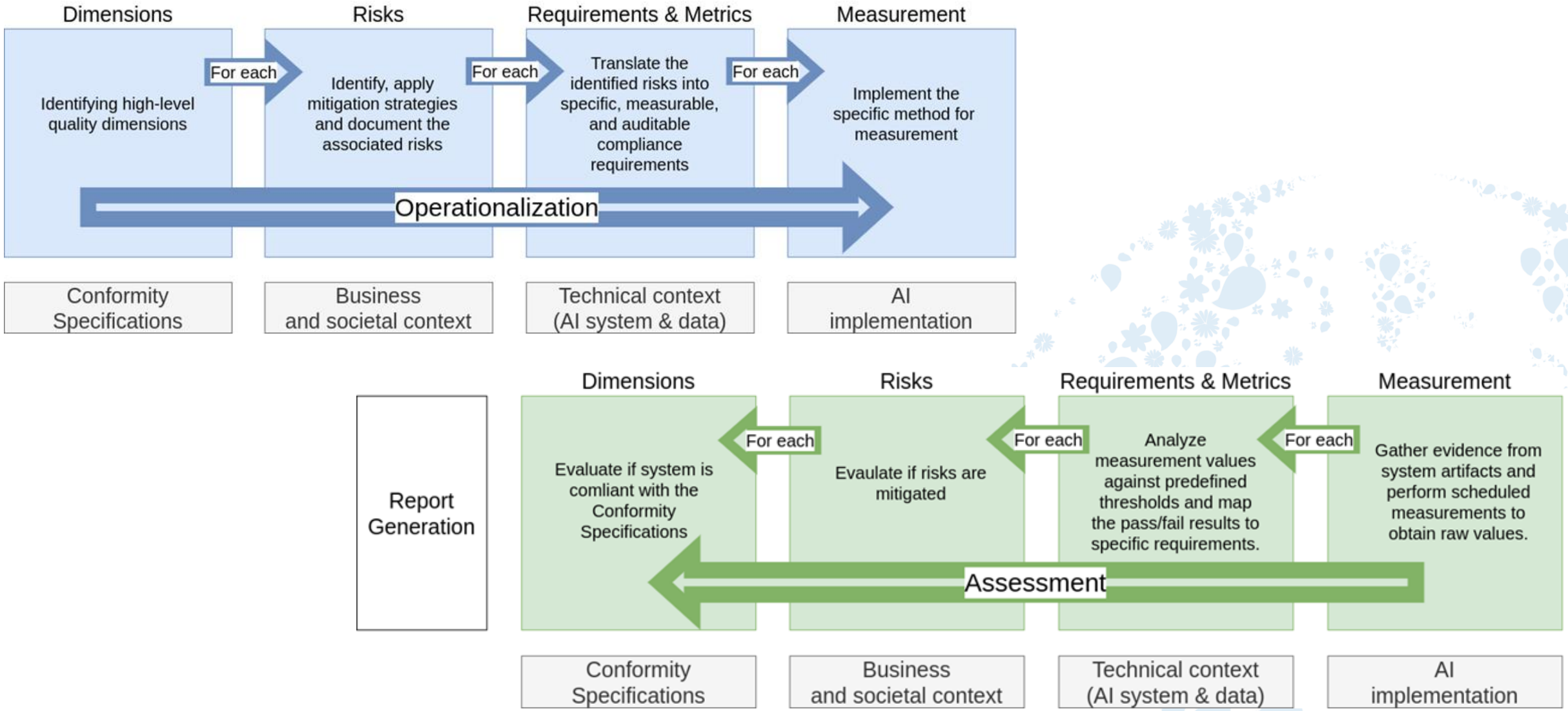
Scope of TS 104008

- Defines the end-to-end CABCA process
- Covers:
  - scoping → operationalization → continuous assessment → documentation/reporting
- **Scoping**: identify applicable conformity specifications (laws/standards/policies)
- **Operationalization**: convert requirements into auditable metrics + measurement setup
- **Continuous assessment**: collect evidence, analyze results, map to requirements
- **Documentation**: ensure traceability and audit-ready outputs



Contents

Operationalisation and Assessment Process in CABCA



Source: ETSI DTS/MTS-104008 “Continuous Auditing-Based Conformity Assessment for AI-enabled systems (**CABCA**)”

Documentation for Trustworthy AI (ETSI TS 104 119)

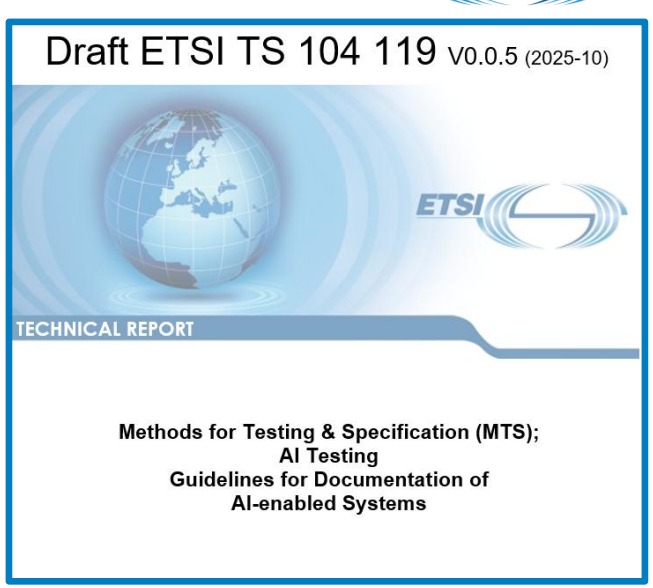
Harmonized Documentation Approach for Trustworthy AI

Motivation

Why should I document at all?

- Fulfill requirements from the project or stakeholders
- Inform stakeholders to increase their trust
- Mitigate risks
- Save cost

Then, what does effective documentation look like?



- **Use Case**: Fulfill obligations of the **EU AI Act**

Proposed Documentation Approach

Top-level Picture

Proposed Documentation Approach

What – Documentation Items

What type of thing shall be documented?

- ML-Data
- ML-Model
- AI System
- AI System Performance, Robustness, Accuracy
- Risks and/or Risk Management Process
- Instructions for use
- ….

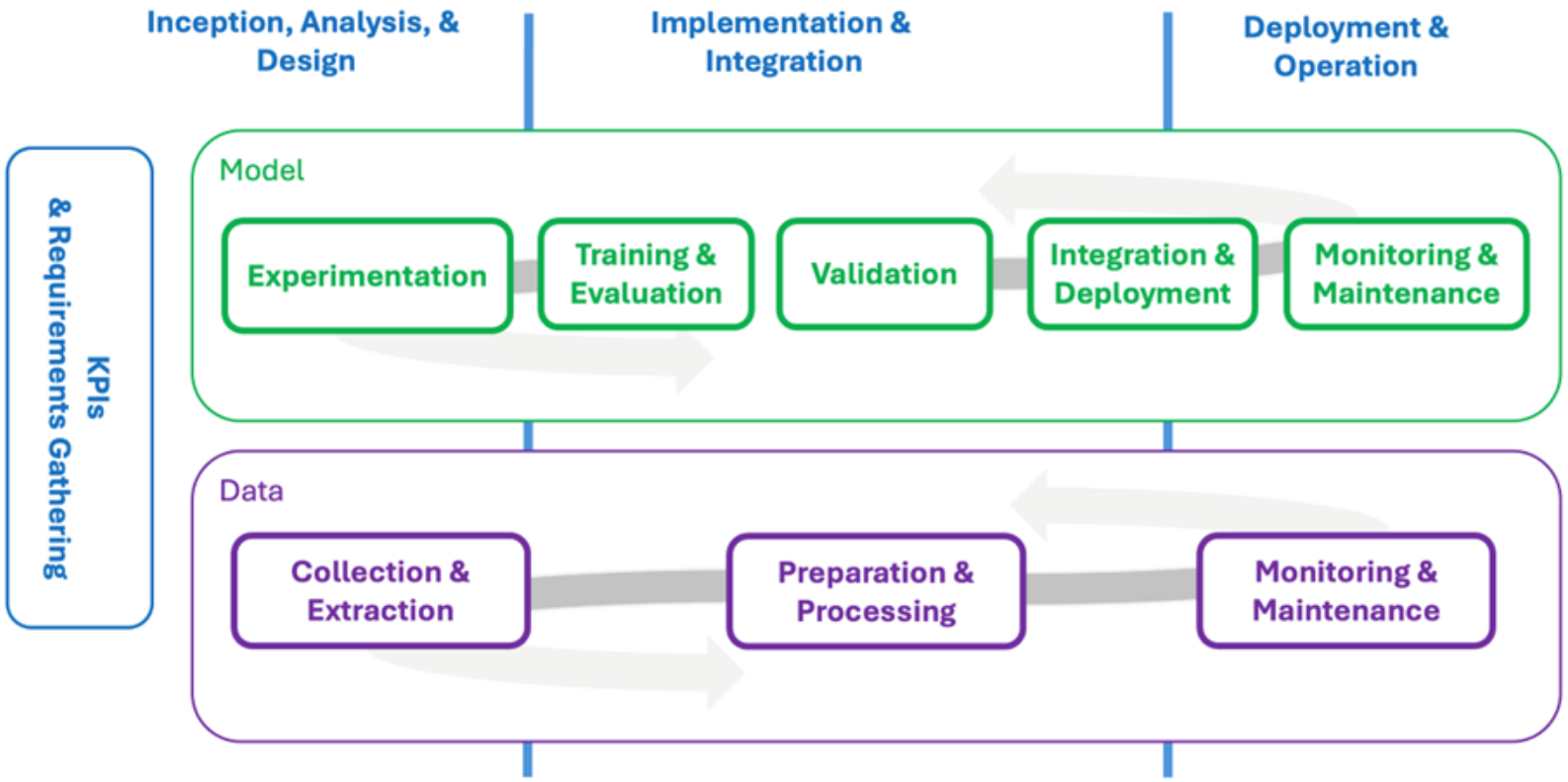
Proposed Documentation Approach

When – AI System Lifecycle

System lifecycle
- Inception, Analysis & Design
- Implementation & Integration
- Deployment & Operation

Model lifecycle
- Experimentation
- Training & Evaluation
- Validation
- Integration & Deployment
- Monitoring & Maintenance

Data lifecycle
- Collection & Extraction
- Preparation & Processing
- Monitoring & Maintenance

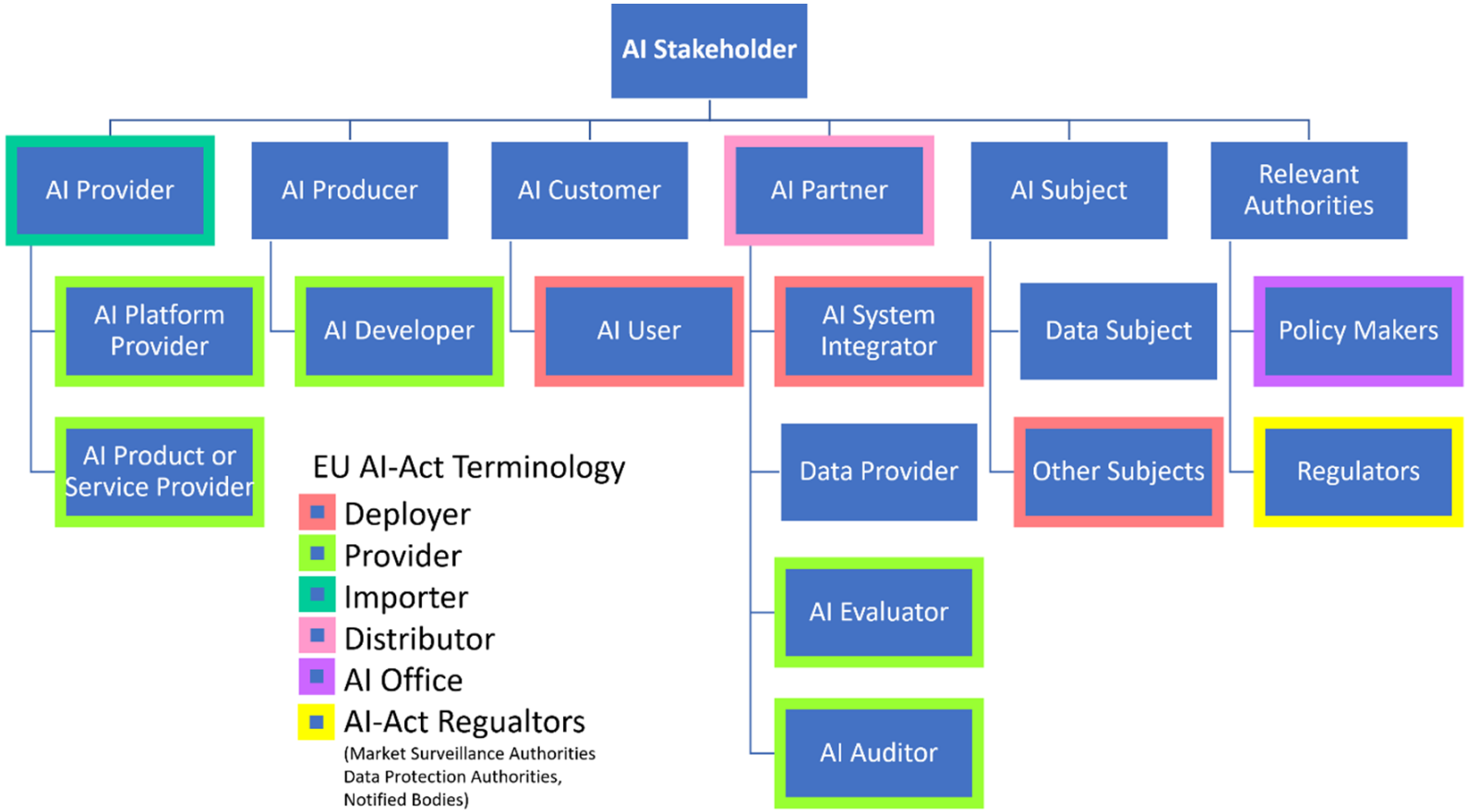


Proposed Documentation Approach

For Whom

Who is the intended audience and who are the stakeholders of the document?

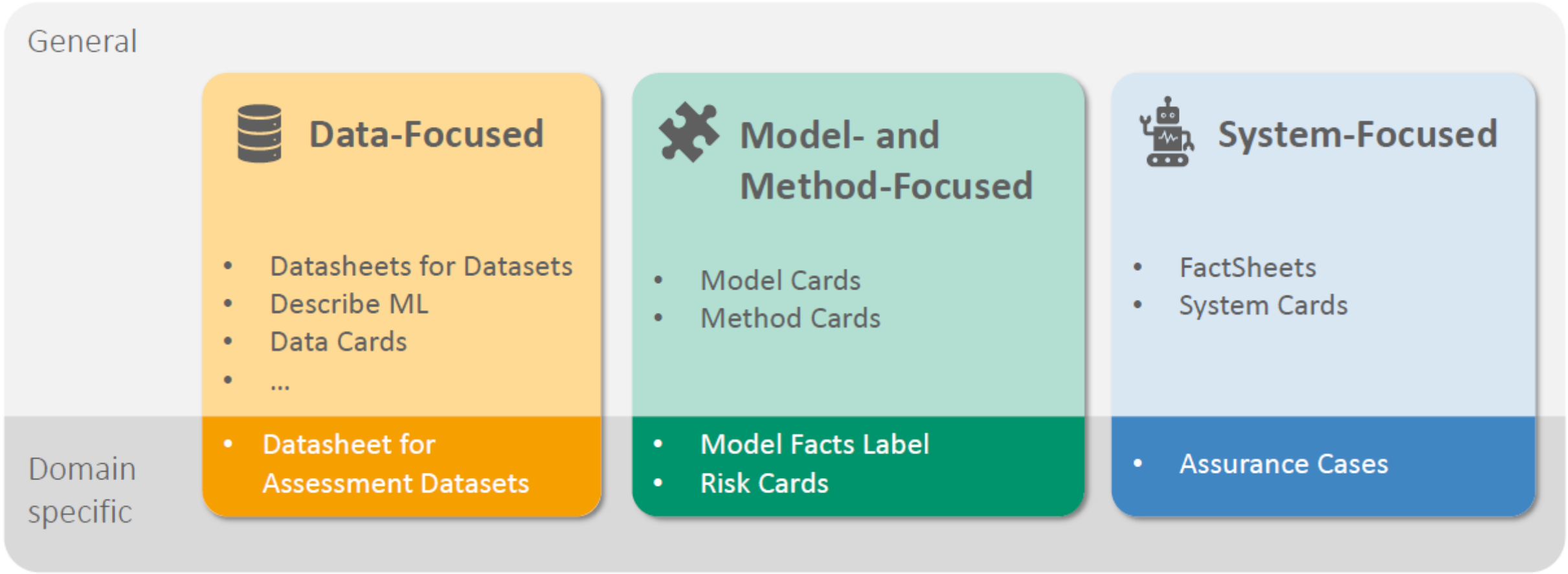
- AI Providers
- AI Producers
- AI Customers
- AI Partner
- AI Subject
- Relevant Authorities
- ....



ISO/IEC 22989:2022 Information technology – AI concepts and terminology https://www.iso.org/standard/74296.html

Proposed Documentation Approach

How – Documentation Techniques with Quality



Proposed Documentation Approach

How – Documentation Techniques with Quality

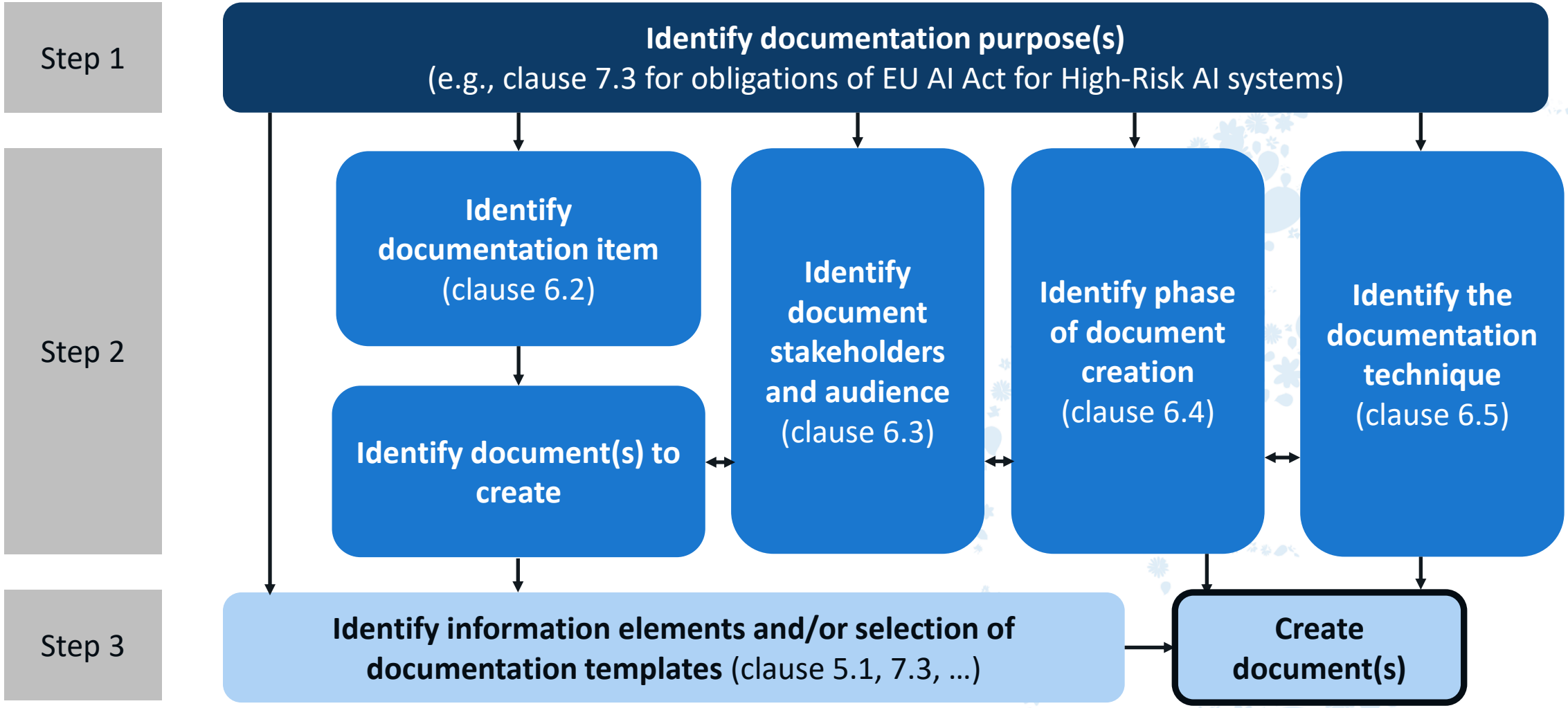
- Mapping of documentation techniques to the documentation approaches
- Documentation techniques aligned with stakeholder needs and responsibilities
- Quality Aspects: Correctness, Consistency, Comprehensibility, Conciseness, Minimalism, Systematic Understanding (see ISO/IEC/IEEE 26514)

ISO/IEC/IEEE 26514:2022
Systems and software engineering — Design and development of information for users

Documentation Approaches	Documentation Technique/Format
Datasheet for Datasets (see Annex D.4.3)	Questionnaire-Based
Model Facts Label (see Annex D.4.1) Model Cards (see Annex D.2.1) Method Card (see Annex D.2.2) Risk Cards (see Annex D.4.2) FactSheets (see Annex D.3.1)	Information Sheet (Static Document)
Dataset Nutrition Label (see Annex D.1.3) Data Cards (see Annex D.1.4)	Interactive Techniques
DescribeML (see Annex D.1.2)	Domain-Specific Language
System Cards (see Annex D.3.2)	Visual Techniques

Proposed Documentation Approach

Structured workflow



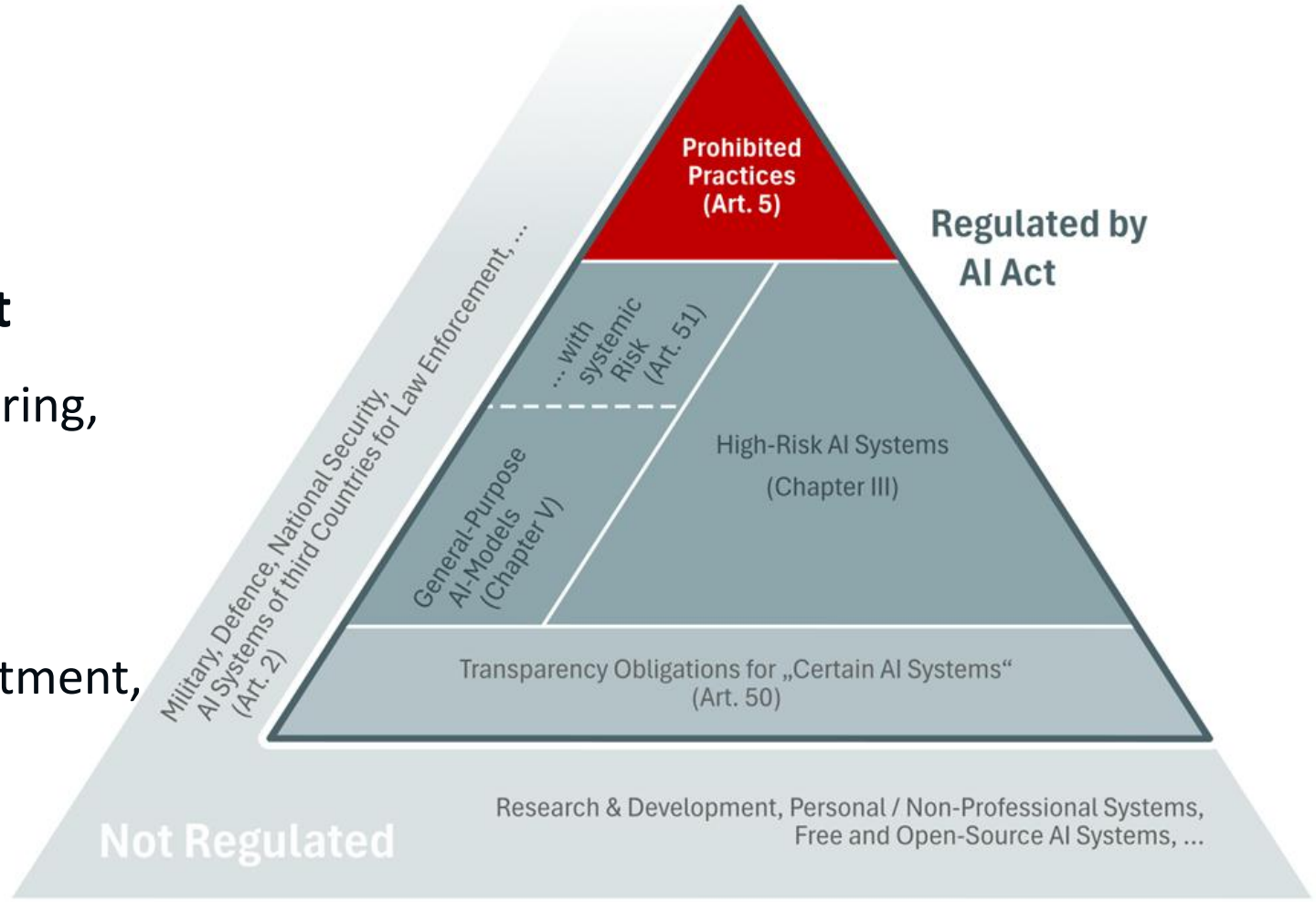
Documentation for Trustworthy AI (ETSI TS 104 119)

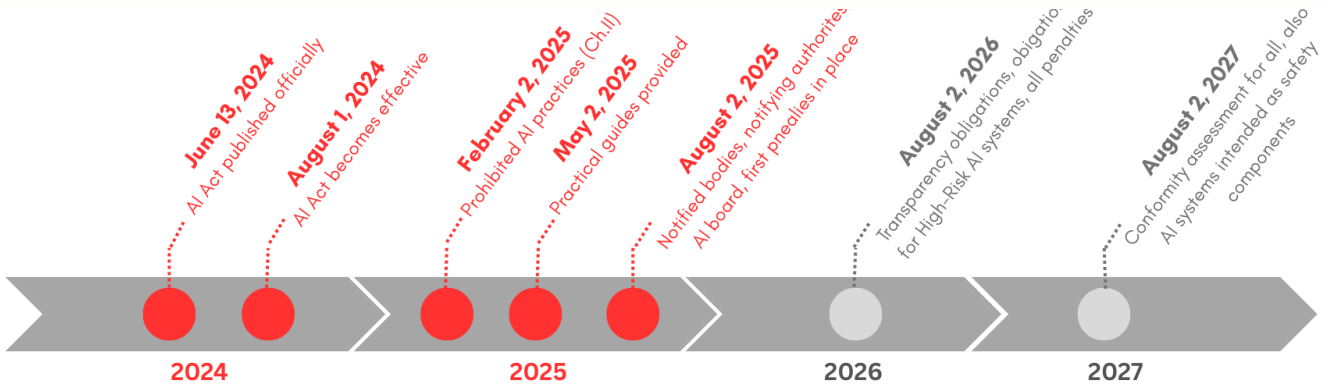
How to document the compliance with the EU AI Act?

European AI Act

A Risk-based Approach

- **Prohibited practices – banned outright**
  - real-time biometric systems, social scoring, manipulation risks like deep fakes
- **High-Risk AI Systems – critical areas**
  - law enforcement, infrastructure, recruitment, and subject to strict compliance and conformity assessment
- **Low-Risk AI Systems**
  - minimal or no risk

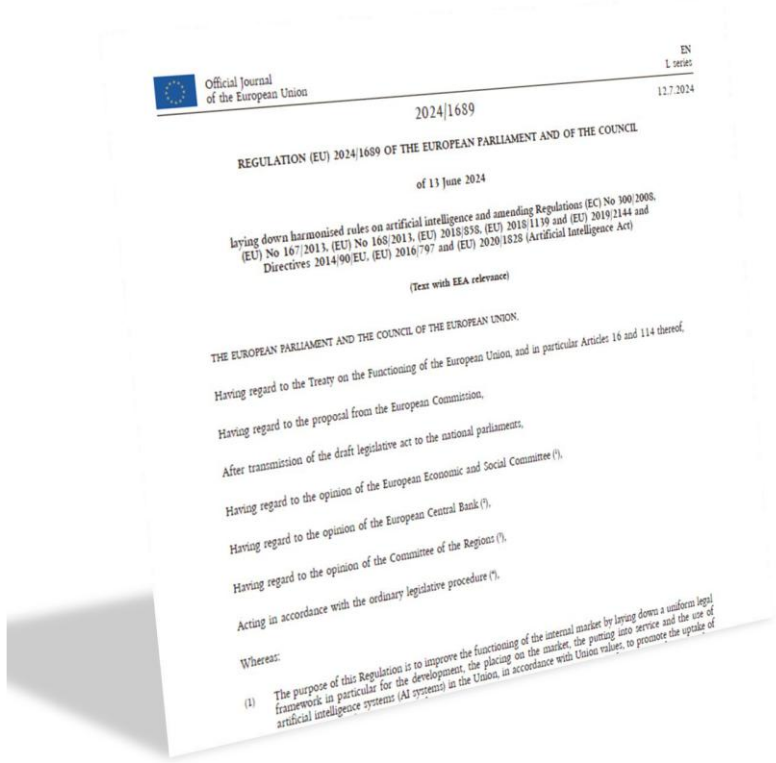




European AI Act

Requirements for Providers -> Documentation

- Risk Management System (Article 9)
- Data governance (Article 10)
- **Technical Documentation (Article 11)**
- Record-keeping (Article 12)
- Transparency (Article 13)
- Human Oversight (Article 14)
- Accuracy (Article 15)
- Robustness (Article 15)
- Cybersecurity (Article 15)


Official Journal of the European Union

EN
L series

12.7.2024

2024/1689

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the European Central Bank (2),

Having regard to the opinion of the Committee of the Regions (3),

Acting in accordance with the ordinary legislative procedure (4),

Whereas:

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union, in accordance with Union values, to promote the uptake of

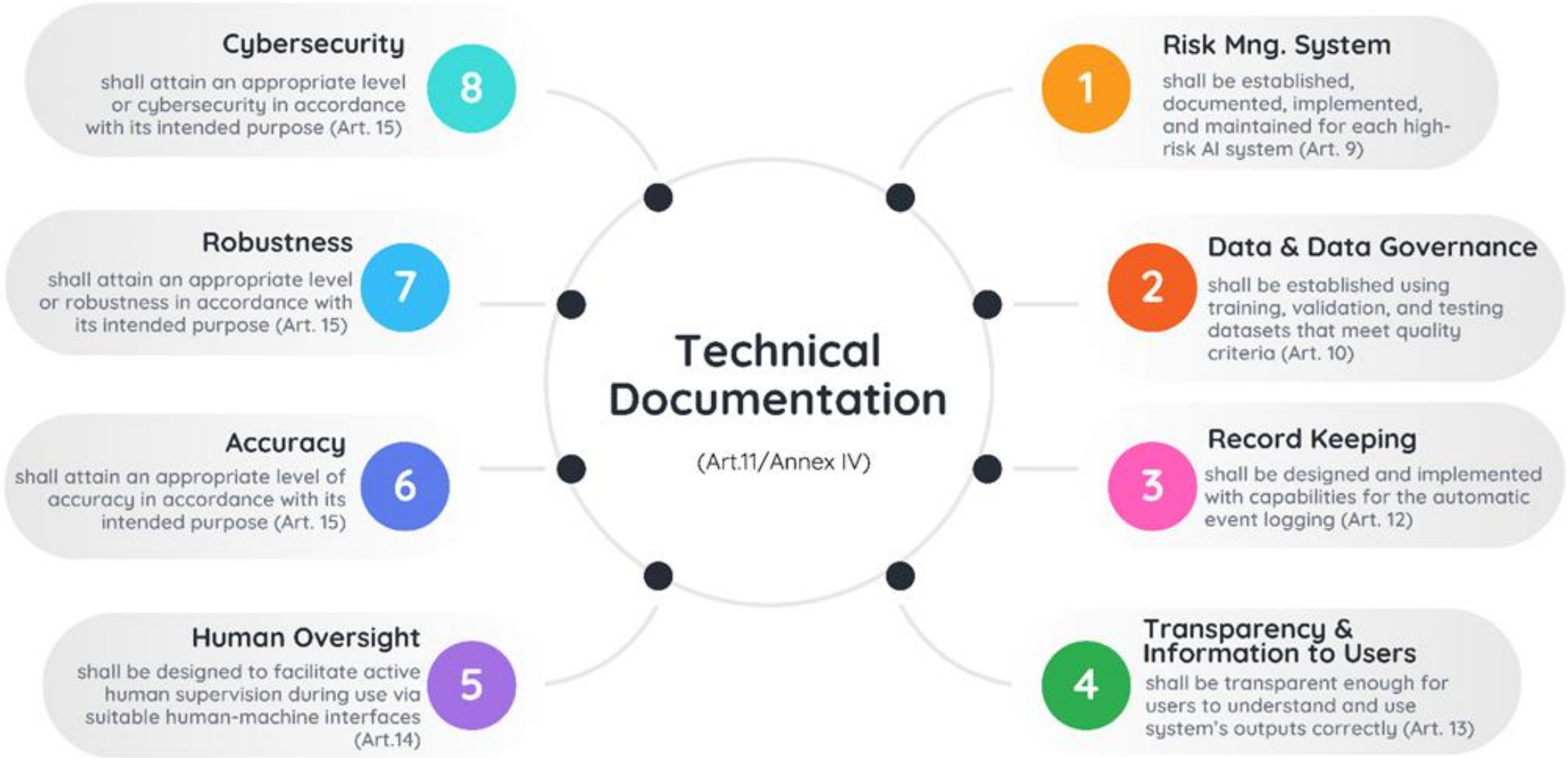
→ Context Requirement

→ Documentation Requirements

→ Recommended Documentation Approaches

European AI Act

Requirements for Providers -> Documentation



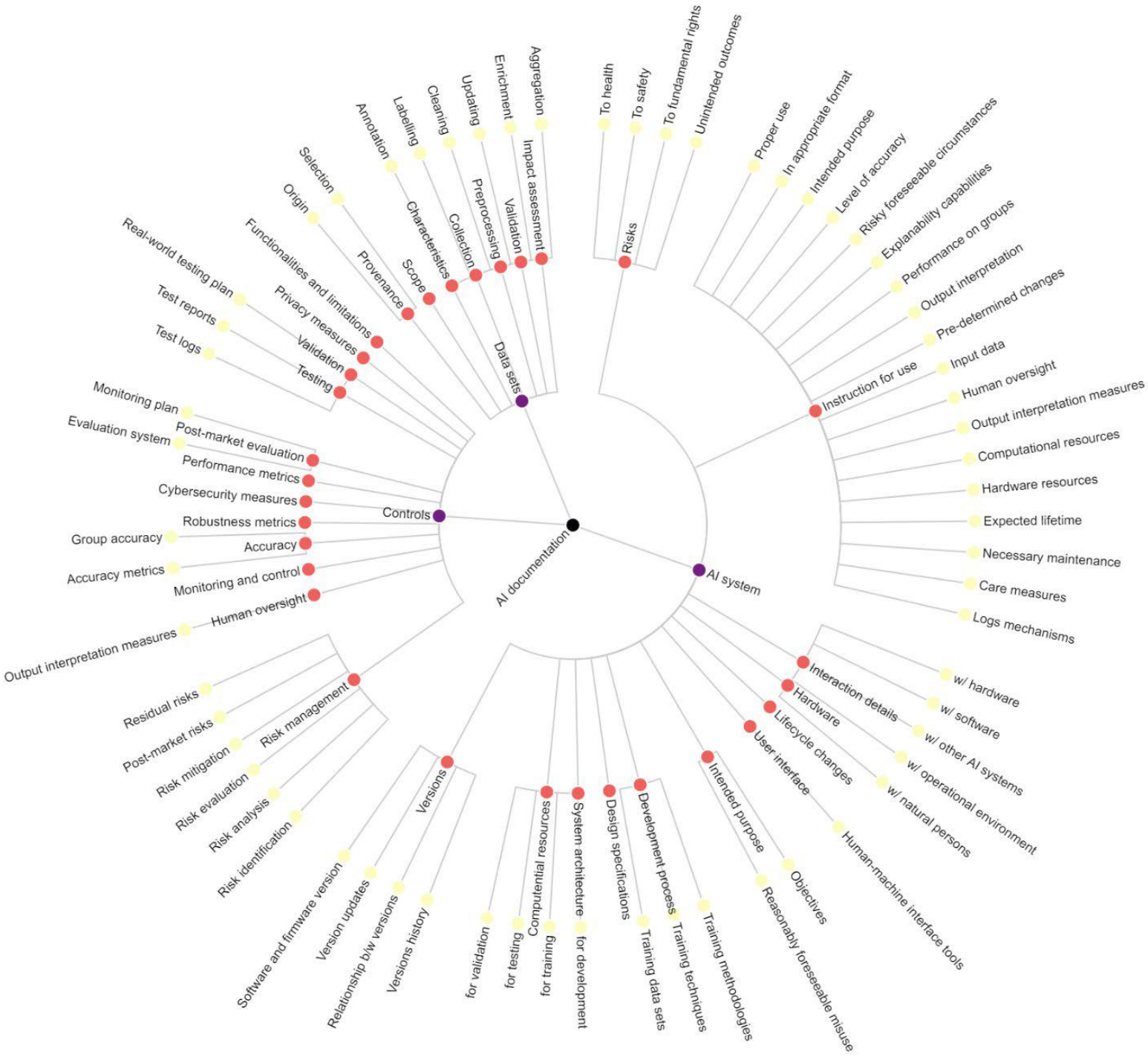
European AI Act

Documentation Requirements

- General System Description
- Design and Development
- Validation and Testing Report
- Cyber-security measures
- .....

Required Information Elements

- AI System
- Data Sets
- Controls

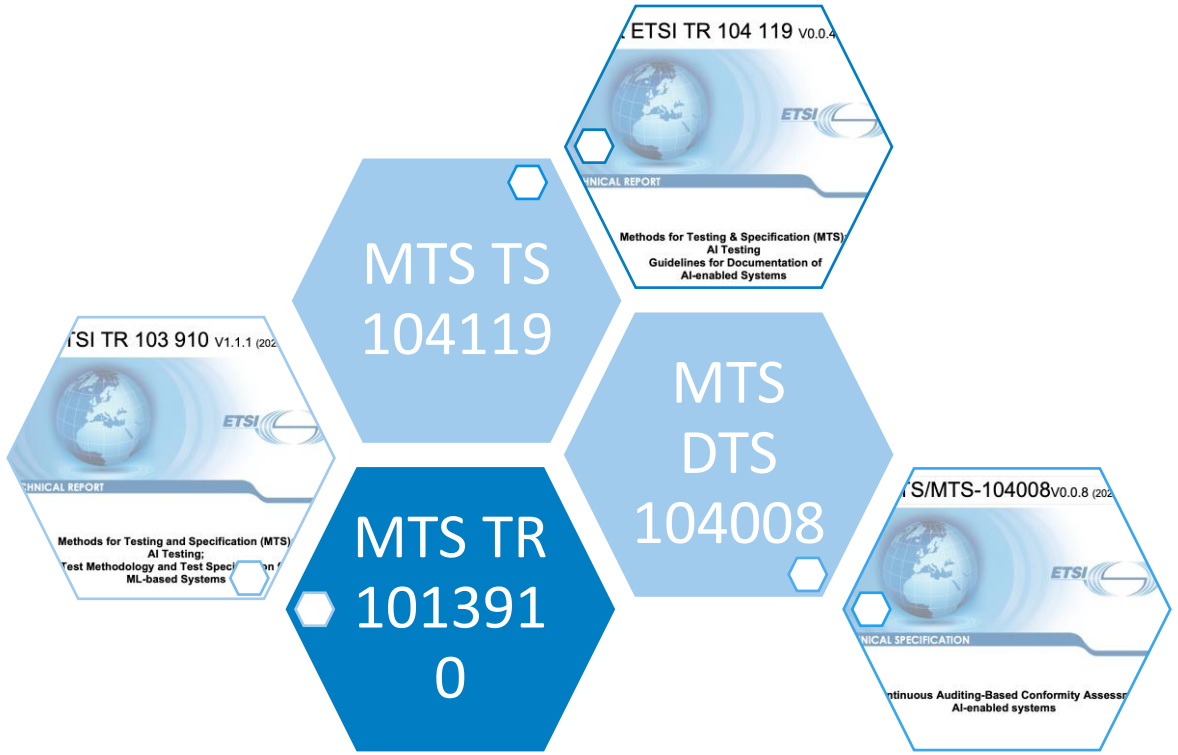


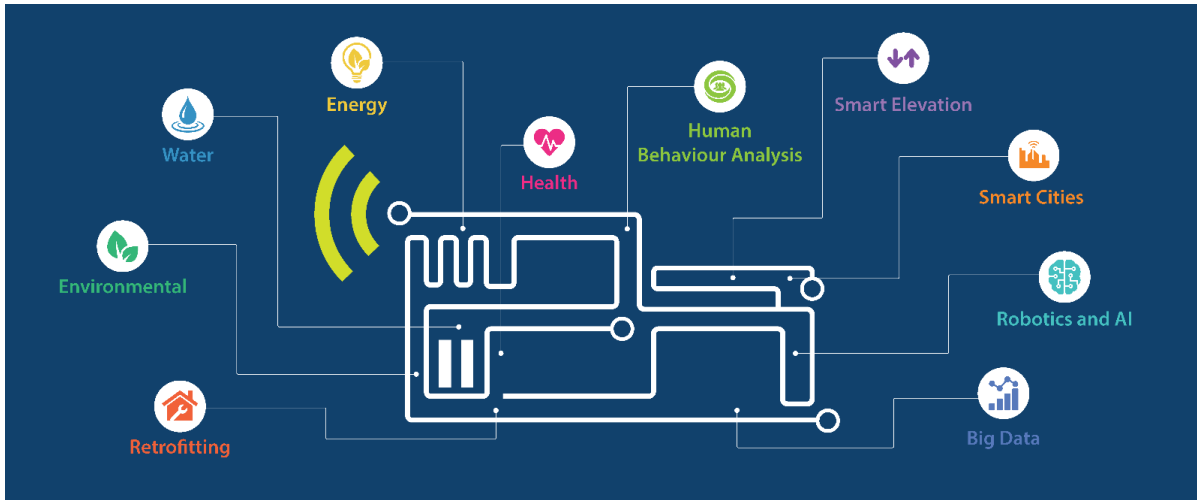
Adoption of ETSI Trustworthy AI Framework

- Integration with the CERTH Smart Home DIH
  - Health care domain

AI4HF

Trustworthy Artificial Intelligence for Personalised Risk Assessment in Chronic Heart Failure





Proposed Documentation Approach

Article 11/Technical Documentation/Design & Development

Step 1

Understand and identify the purpose of the documentation artifacts

Purpose: To communicate essential technical and ethical information about the QA model

Step 2

Identify the selected documentation aspects per document

Documentation Item (Clause 6.2): QA Model (based on two LLMs with Chroma DB)

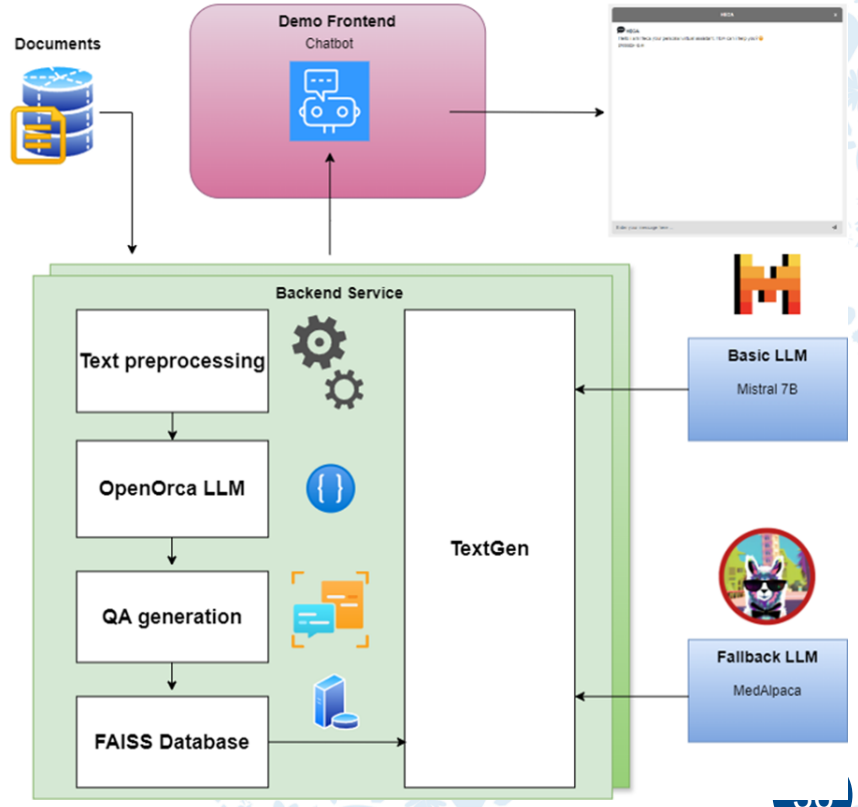
Documentation Stakeholder (Clause 6.3): Provider (AI Developer)

Phase of Documentation (Clause 6.4): Implementation & Integration (Model Training, Evaluation, and Deployment)

Documentation Technique (Clause 6.5, D2.1): Model Card in structured tabular format

Step 3

Identify the document contents (information elements) and create/assemble the document/Document: *Model Card for QA Model*



Proposed Documentation Approach

Annex A1 Health Care Use Case /Sample Documentation Scenarios

Document: *Model Card for QA Model*

- Model Overview
- Purpose
- Model details
- Evaluation & Performance
- Ethical Consideration
- Maintenance & Update
- Contact & Governance

Model Overview	
Name	HECA V2 QA Model
Version	HECA Version B
Description	The QA Model is a core component of the HECA V2 Virtual Assistant. It enables the system to generate domain-specific, context-aware answers to healthcare-related queries by retrieving and processing QA pairs derived from curated medical documents.
Purpose	
Intended Use	The QA Model component is designed to automatically generate high-quality Question-Answer (QA) pairs from curated healthcare-related documents, enabling efficient semantic retrieval and explainable conversational support within the HECA V2 Virtual Assistant.

Realizable Capabilities

Sense		Process Knowledge		Act		Communicate	
Visual	☐	Factual	■	Physical	☐	Visual	☐
Auditory	☐	Procedural	☐	Non-physical (Agents)	☐	Auditory	☐
Olfactory	☐	Conceptual	■			Olfactory	☐
Gustatory	☐	Metacognitive	☐			Tactile	☐
Tactile	☐					Textual	■
…	☐					Gestural	☐

Primary Users	Researchers, health professionals, patients
Use Cases	Conversational support for healthcare education, research assistance, clinical support (non-decision-making).
Domain	Healthcare, with a focus on chronic heart failure
Usage Scope	Public-facing web application, accessible globally via browser.
Model Details	
Architecture	Hybrid retrieval-generation architecture using: 1) OpenOrca LLM to generate QA pairs during training; 2) FAISS-based semantic retrieval engine; 3) Textgen module with Mistral 7B and MedAlpaca LLMs to generate responses.

Next steps

TTF 038 (2024-2025) delivered:

- Analysis of AI Act documentation requirements & related standards
- Survey of existing industry documentation practices
- Recommendations for a harmonized documentation approach

Looking Ahead

- **2026:**

  Apply and validate documentation scheme through sector-specific use cases & practical templates;

  Multi-Agent Reference Architecture for Automated AI Compliance (ENACT project)
- **2027:** Refine quality attributes, metrics, and evaluation measures
- **2028:** Define human- & machine-readable formats and interface specifications

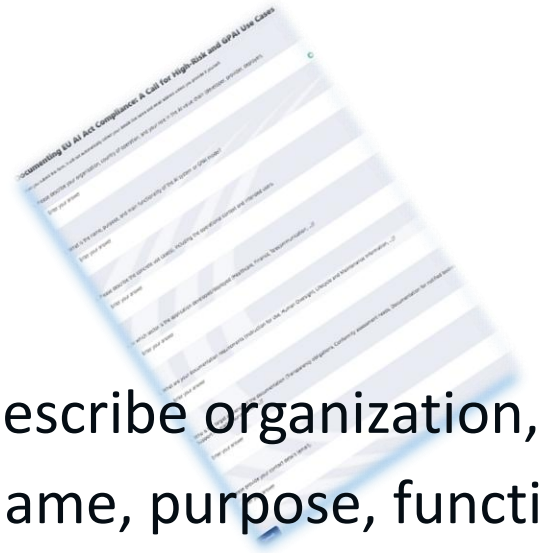
Call for High-Risk and GPAI Use Cases

TTF 058: Evaluation and Enhancement of the Harmonized Documentation Approach

- ETSI TC MTS / WG AI has launched a project to further develop Technical Report TR 104 119
- Objective: validate the AI documentation approach through selected High-Risk AI and GPAI use cases
- Participants are invited to submit use cases and corresponding requirements via a questionnaire
- In return, contributors will receive EU AI Act–compliant documentation

More information at:

https://portal.etsi.org/TB-SiteMap/MTS/Call-for-Use-Cases



Call for High-Risk and GPAI Use Cases

- Describe organization, country, role in AI value chain
- Name, purpose, functionality of the AI system or GPAI model
- Describe use cases, operational context, and users
- Sector (Healthcare, Finance, Telecommunications)
- Documentation requirements (Human oversight, Robustness..)
- Target audience of the documentation
- Contact details

Interested?

Get more information and contribute!

- **Attend an MTS meeting as ETSI member or as a guest of TC MTS**
  - Three annual meetings at different locations
- **Actively work in Task Force (STF or TTF) teams**
  - Usually running 2-3 different STFs / TTFs
- **Contribute your interests or needs in testing**
  - E.g. related to emerging fields such as testing of and with AI

Contact ETSI TC MTS AI

TC MTS WG AI Portal:
https://portal.etsi.org/MTS

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Thank you for your attention

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and **join MTS AI**

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