



**AI Assurance
Institute**

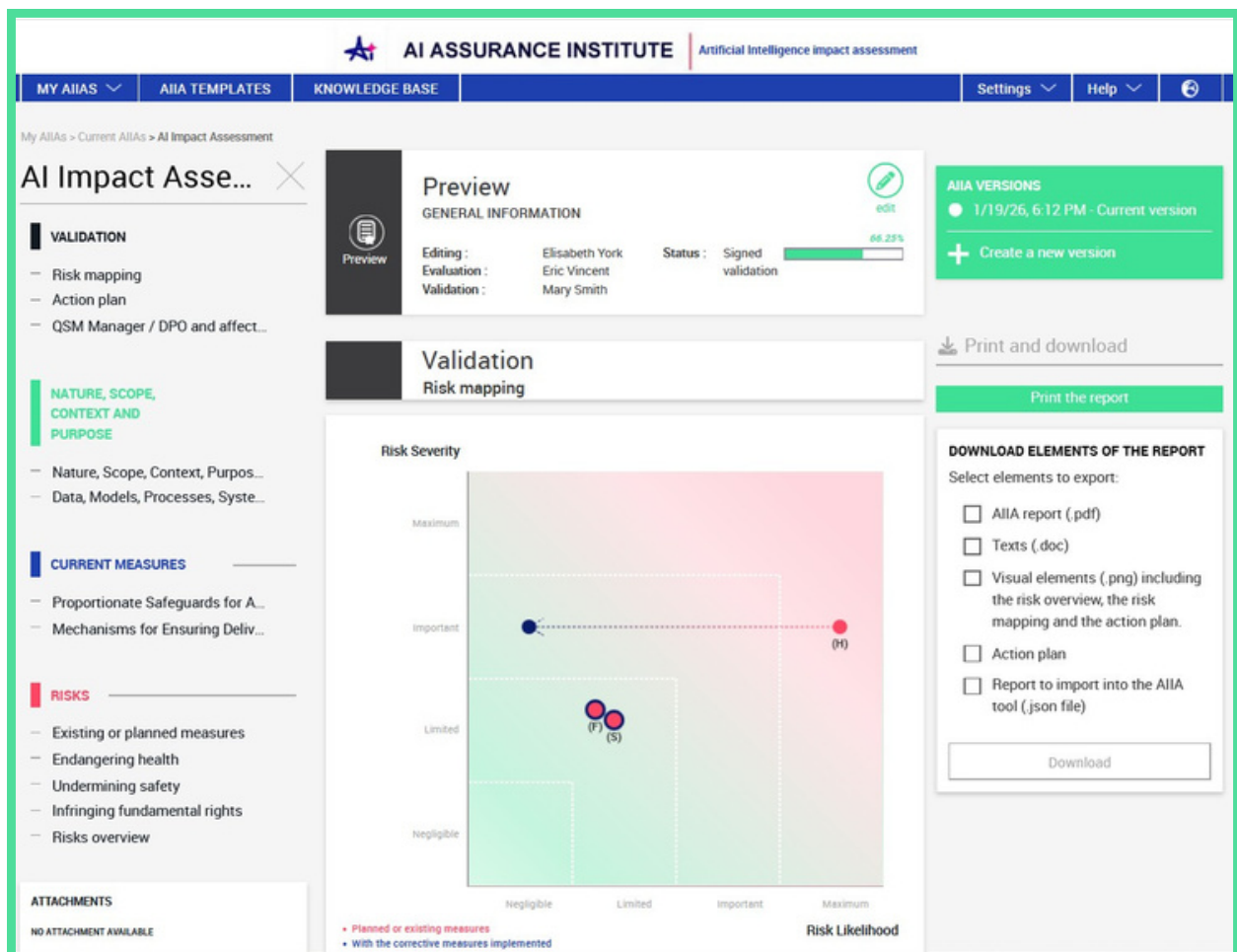
AI IMPACT ASSESSMENT

AIIA – AI Impact Assessment Tool

Comprehensive Compliance Solution for High-Risk AI Systems under the EU AI Act

Overview

AIIA is a professional-grade software platform specifically designed to support organisations in achieving and demonstrating compliance with the EU Artificial Intelligence Act (Regulation (EU) 2024/1689) for high-risk AI systems. It provides a structured, auditable, and collaborative framework that integrates regulatory obligations from the AI Act, GDPR, and harmonised standards, including prEN 18286 (Quality Management Systems for AI).



The tool guides users through a systematic assessment process structured around three core pillars:

- **Proportionality, Necessity, and Foundational Controls** – Ensuring minimal, purpose-bound processing and robust baseline safeguards.
- **Operational Rights Delivery, Transparency, and Oversight** – Guaranteeing effective exercise of data subject rights, clear information provision, and meaningful human oversight.
- **Broad Compliance Assessment, Governance, Risk, Security, and Sustainability** – Embedding enterprise-wide governance, lifecycle risk management, cybersecurity, and environmental responsibility.

Multi-role collaboration (preparer, reviewer, approver) enables cross-functional teams and external parties (e.g., providers, suppliers) to contribute to system description, technical documentation, risk assessment, control implementation, and final acceptance.

AIIA focuses on pre-market readiness, generating the documentation and evidence required for conformity assessment, technical documentation (Annex IV), EU declaration of conformity, and regulatory audits.

IA Demonstrati...

VALIDATION

- Risk mapping
- **Action plan**
- QSM Manager / DPO and affected persons' opinions

NATURE, SCOPE, CONTEXT AND PURPOSE

- Nature, Scope, Context, Purpose & Interests at Stake
- Data, Models, Processes, Systems, Infrastructure and Technical Documentation

CURRENT MEASURES

- Proportionate Safeguards for Achieving Effective Protection of Health, Safety, and Fundamental Rights
- Mechanisms for Ensuring Delivery of Mandated Operational Performance Requirements

RISKS

- Existing or planned measures
- Endangering health
- Undermining safety
- Infringing fundamental rights

Overview

Mandatory Protections

ACCOUNTABILITY	
Purpose Specification	
Lawfulness	
Fairness and Transparency	
Necessity and Proportionality	
Data Minimisation	
Data Accuracy	
Storage Limitation	
Organisational Measures	
Technical Safeguards	
QUALITY MANAGEMENT SYSTEM	
Risk Management System	
Data and Data Governance	
Human Oversight	
Robustness measures	
Cybersecurity measures	
Transparency with deployers	
Affected Persons Notification	
Lifecycle Rights Mitigation	
GPAP Rights Safeguards	
GPAP Model Rights Impact	
Internal Governance Framework	
Complaints & Resolution	
FRIA Execution Process	
Transparency & Explainability	
Bias Detection & Mitigation	
Prohibited Practices Controls	
Legitimate Interest Assessment	
Consent Validity & Management	
Access & Portability Rights	
Rectification & Erasure Rights	
Restriction & Objection Rights	
Processor Obligations & Control	
Intern. Transfers Safeguards	
Privacy by Design & Default	
GDPR Compliance Maintenance	
Anonymisation Applications	
Data Scraping Risk Mitigation	
Risk Management System	
Deployer Residual Risk Assured	
Operation Control Effectiveness	

Planned or existing measures

Encryption	
Data partitioning	
Logical access control	
Traceability	
Integrity control	
Archiving	
Operational security	
Malware protection	
Workstation management	
Website security	
Backups	
Maintenance	
Computer network security	
Monitoring	
Physical access control	
Hardware security	
Risk source isolation	
Protection against non-human risk sources	
Organization	
Policy (rule management)	
Project management	
Third-party relations	
Supervision	

Risks

Health	
Safety	
Fundamental Rights	

AIIA VERSIONS

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+ Create a new version

Print and download

Print the report

DOWNLOAD ELEMENTS OF THE REPORT

Select elements to export:

- ☐ AIIA report (.pdf)
- ☐ Texts (.doc)
- ☐ Visual elements (.png) including the risk overview, the risk mapping and the action plan.
- ☐ Action plan
- ☐ Report to import into the AIIA tool (.json file)

Download

Key Features

- **Comprehensive Regulatory Roadmap** Step-by-step guidance covering all high-risk AI obligations, from classification and technical documentation to post-market monitoring and serious incident reporting.
- **Precise Regulatory Referencing** Every question links directly to specific AI Act articles, GDPR provisions, and harmonised standards (e.g., prEN 18286, prEN 18284, prEN 18283), with required mandatory documents and objective evidence clearly identified.
- **Automated Traceability & Gap Analysis** Real-time visibility of compliance coverage; automated traceability matrices linking answers to regulatory requirements; instant identification of gaps.
- **One-Click Documentation Generation** From user responses, AIIA automatically generates audit-ready outputs including:
 - Technical Documentation (Annex IV compliant)
 - EU Declaration of Conformity (Annex V)
 - Fundamental Rights Impact Assessment (FRIA – Art. 27)
 - Post-Market Monitoring Plan (Art. 72)
 - Residual Risk Acceptance Statement
- **Integrated FRIA & Lifecycle Risk Management** Dedicated modules for Fundamental Rights Impact Assessment, continuous risk management (Art. 9), and post-market monitoring with closed-loop feedback to design and mitigation controls.
- **Sustainability & Resource Tracking** Built-in monitoring of energy consumption, carbon footprint, and environmental impact, supporting responsible AI deployment.
- **Secure Multi-User Collaboration** Role-based access, version control and secure exchange of documentation with external parties.
- **Extensive Knowledge Base** Curated regulatory guidance, recommended controls, templates, and best practices continuously updated by compliance experts.



Benefits

- **Regulatory Confidence** – Structured, evidence-based approach minimises compliance risk and prepares for notified body or authority scrutiny.
- **Efficiency** – Reduces manual documentation effort by up to 80% through automation and reusable templates.
- **Collaboration** – Enables seamless teamwork across technical, legal, compliance, and executive functions.
- **Scalability** – Suitable for single systems or enterprise-wide AI portfolios.
- **Future-Proof** – Regularly updated for new standards, codes of practice, and regulatory developments.

Target Users

- AI System Providers & Manufacturers
- Deployers of High-Risk AI Systems
- Quality & Compliance Managers
- Risk & Data Protection Officers
- Legal & Regulatory Affairs Teams
- Internal Auditors & Conformity Coordinators
- Notified Bodies & Consultants

Availability

AIIA is delivered as a secure, cloud-based SaaS platform with enterprise-grade security, regular updates, and dedicated support.

Contact: info@aiassurance.institute Website: www.aiassurance.institute

AIIA – Your trusted partner for responsible, compliant, and ethical AI deployment in the European Union.