GETTING READY FOR TRUSTWORTHY AI REGULATION

HOW TO ANTICIPATE
THE EU REGULATORY FRAMEWORK FOR AI

AI CoE Insights

Context

As the market is experiencing exponential **digital intelligence** advancements with AI systems becoming more complex, the European Union seeks to promote an unprecedented legislative framework that will provide a solid legal basis and a coordinated European approach for designing and developing **trustworthy human-centered AI systems.**

On the 21st of April 2021, the European Commission published the long-awaited regulation proposal, known as the AI Act, **governing the use of AI systems regarding their level of risk** (prohibited uses, high-risk, limited-risk, and low risk). The proposal establishes horizontal proportional requirements that will ensure the proper development of trustworthy AI systems.

This regulation has the ambition to harmonize the existing EU laws to facilitate investment and innovation in AI while protecting the individuals' fundamental rights and principles on which the EU is founded when developing AI systems.

TO WHOM IS THIS REGULATION APPLICABLE?

The AI Act applies to everyone who wants to develop, distribute and import AI systems in the EU market or to systems that affect users located in the EU territory.

Today's Challenges

The AI Act identifies eight different mandatory requirements to design and develop trustworthy High-Risk AI systems:

🛡️	Risk Management	Art. 9
🛡️	Data and Data Governance	Art. 10
📲	Record-keeping	Art. 12
👁️	Transparency and Provision of Information to Users	Art. 13
🧑‍💻	Human Oversight	Art. 14
🔒	Accuracy, Robustness and Cybersecurity	Art. 15
📄	Technical Documentation	Art. 11
🔷	Conformity Assessment	Art. 19

Approaching all the AI Act's requirements can be overwhelming, as each one of them presents **different complexities** and require unique approaches to comply with the regulation successfully.

The Regulation also encourages providers of **non-high-risk AI systems** to implement a **code of conduct** to voluntarily apply the mandatory requirements for high-risk AI system.

AI REGULATION ALIGNMENT, TO BE A LEADER OR A FOLLOWER?

At everis, we are aware of the dilemma an organization faces in overcoming these challenges, especially when adapting the AI systems' design and development processes to the new regulatory provisions.

For that reason, we look forward to supporting organizations to start ahead at defining the Trustworthy AI journey and transform the challenges into a new competitive advantage by harnessing our Responsible AI-driven solutions and methodologies with an end-to-end approach aligned with the provisions of the new AI regulation.

Moreover, organizations will benefit from boosting their ongoing AI performance, maximizing and scaling the value of their AI systems, spreading the best practices on AI across the company, and positioning as a market leader on state-of-the-art technologies.

Risk Management

REQUIREMENT BREAKDOWN

In order to develop a trustworthy AI system free of errors and perils, the regulation pays special attention to the proper management of risks and biases throughout the entire AI system's lifecycle, from the birth of the AI-driven initiative until the monitoring phase.

Thus, according to this provision, organizations and providers of high-risk AI systems that look forward to remaining efficient and risk-free must leverage a Risk Management System, which must include the following:

01 **Identification and analysis** of the known and foreseeable risks associated with each high-risk AI system

02 **Evaluation of other possibly arising risks** based on the analysis of data gathered from the post-market monitoring system

03 **Estimation and evaluation** of the risks when the high-risk AI system is used in accordance with its intended purpose

04 **Adoption of suitable risk management measures,** such as:
- Elimination or reduction of risks through design and development
- Implementation of adequate mitigation and control measures
- Implementation of transparency measures

KEY STEPS TOWARDS COMPLIANCE

Successfully deploying AI compliance initiatives requires AI stakeholders' strategic alignment to develop an end-to-end AI risk management system. As a starting point, designing an AI risk classification should serve as the backbone for the compliance strategy, defining the mechanisms to be implemented across the AI lifecycle.

To support our clients, we've structured a **Risk Management Methodology embedded in our AI Governance Practice** to identify, evaluate, mitigate existing and future-prone risks and biases.

Operating a risk management system on an ongoing basis not only requires deploying specific control mechanisms and documentation but also should serve as a tool that is further iterated throughout the design, development, and monitoring of AI systems.

AI RISKS CLASSIFICATION

Birth of the Initiative
- Scope definition
- Stakeholders impact

Data Preparation
- Data privacy
- Data quality
- Data sampling bias

Development
- Governed experimentation
- Explainability

Implementation
- Model validation
- Implementation errors

Use
- Data drift
- Performance decay
- Deviation from intended purpose
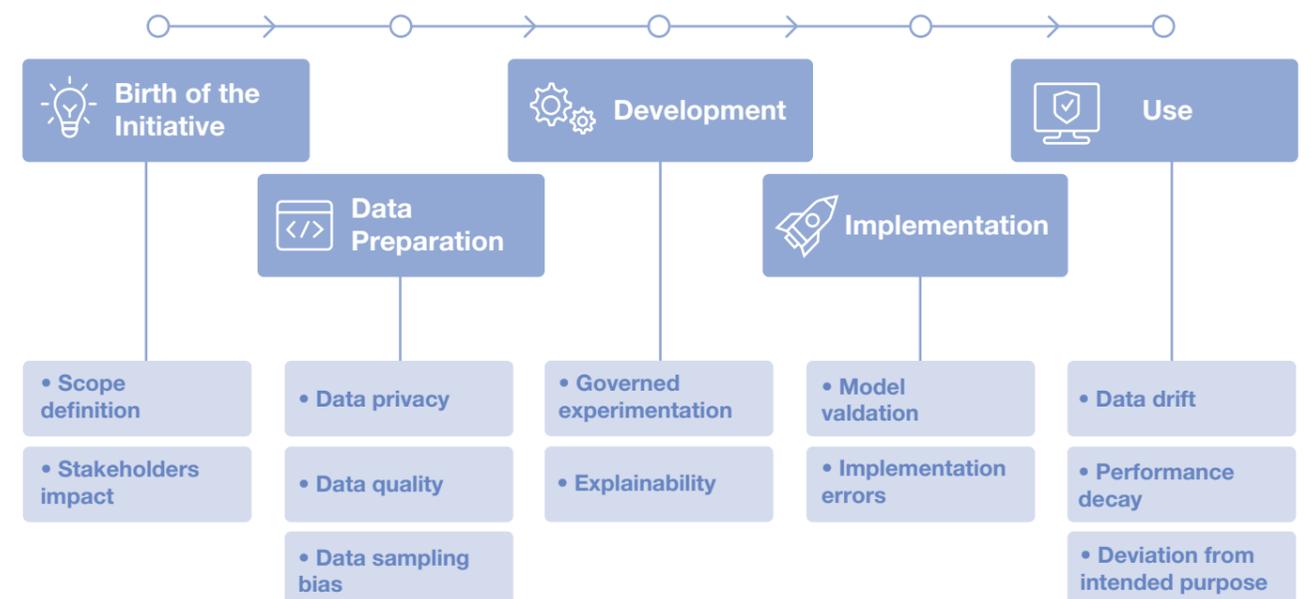
Data and Data Governance

REQUIREMENT BREAKDOWN

The new AI regulation emphasizes a relevant aspect for building trustworthy AI models with reliable outcomes: Data and Data Governance.

This provision defines the elements and **characteristics** to be considered for achieving **high-quality data** when creating your training and testing sets.

Additionally, it demands organizations to deploy a **responsible data governance** that **oversees the end-to-end data lifecycle** to ensure risk-free and trustworthy data sets to build resilient AI models and with reliable solutions.

THE FOUR KEY CHARACTERISTICS OF DATA & DATA GOVERNANCE:

RELEVANT

Relevant, representative, free of errors and complete data.

SUITABLE

Integrate appropriate statistical properties regarding the individuals on which the HRAIS* is intended to be used.

INCLUSIVE

Include the specific geographical, behavioral or functional characteristics or elements within which the HRAIS is intended to be used.

COMPLIANT

Comply with the rest of the EU laws (such as GDPR) to appropriate safeguard the individuals' fundamental rights and freedoms.

*HRAIS: High Risk AI System

KEY STEPS TOWARDS COMPLIANCE

While data governance processes are well established in data-driven organizations, AI has added a new layer of complexity to data transformation that needs to be separately addressed. To ensure a consistent, high-quality standard for all features across model training and model consumption, we´ve defined a Data Transformation Framework for AI as a mechanism to meet data quality and integrity standards across the AI lifecycle.

This framework should also be complemented with Fairness & XAI methodologies, to be incorporated during the development process favoring data representativeness as well as supporting model's interpretability.

DATA TRANSFORMATION FRAMEWORK FOR AI

Define the standards, techniques and documentation needs to be incorporated during AI development.

The Feature store serves as a central repository for Data Scientist to: discover, define, store, share and reuse features.

DATA PREPROCESSING → FEATURE TRANSFORMATION → FEATURE STORE

Model Training

Model Consumption
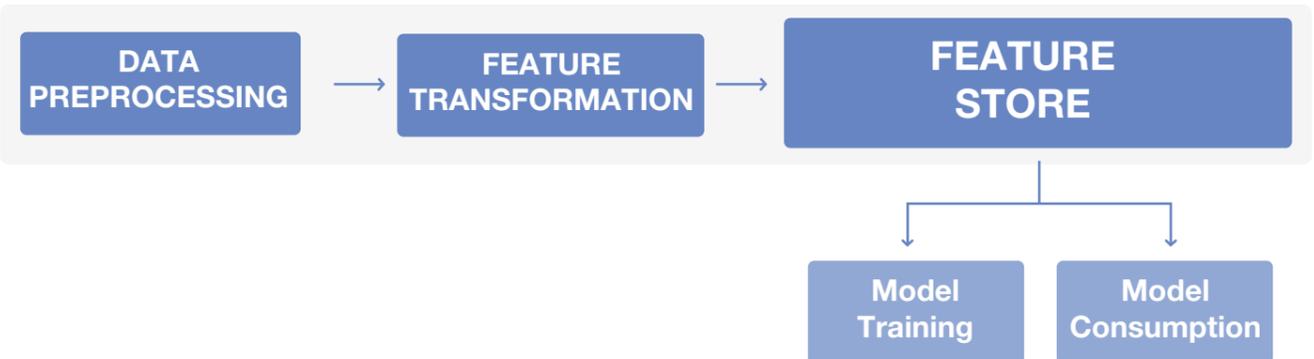
FEATURE STORE

Prevents from:
- Inability to reproduce results
- Redundant features from multiple AI teams
- Inadequate features transformation
- Lower AI teams productivity related to high data transformation workload

Fosters:
- Centralized access to data for AI applications
- Stable Data Pipeline for feature serving
- Single source of truth for features definition
- Data lineage preservation

Record-keeping

REQUIREMENT BREAKDOWN

As the AI regulation states, it is paramount that in the design and development stages of High-risk AI systems, organizations include capabilities for enabling the automatic recording of events and activities ('logs') while the AI system is operating.


KEY STEPS TOWARDS COMPLIANCE

Facilitating audit trails for AI systems requires dedicated toolchain and processes to be integrated within the AI architecture platform, enabling the recording and monitoring of all the events generated by the model throughout its lifecycle.

In order to deploy efficient log management, KPIs need to be defined at an early stage to create actionable notifications and alerts based on these metrics.

Within our AI architecture practice, we recommend implementing the centralization of logs and its management within the Audits & Alert module of the MLOps Architecture, facilitating its automated end-to-end tracking.

Facilitate the post-market monitoring and documentation process to **evaluate the continuous compliance of AI systems**

Enable the **monitoring** of the operation with respect to the occurrence of risks and pitfalls

Ensure the proper **traceability** of the AI system's functioning throughout its entire lifecycle according to its intended purpose
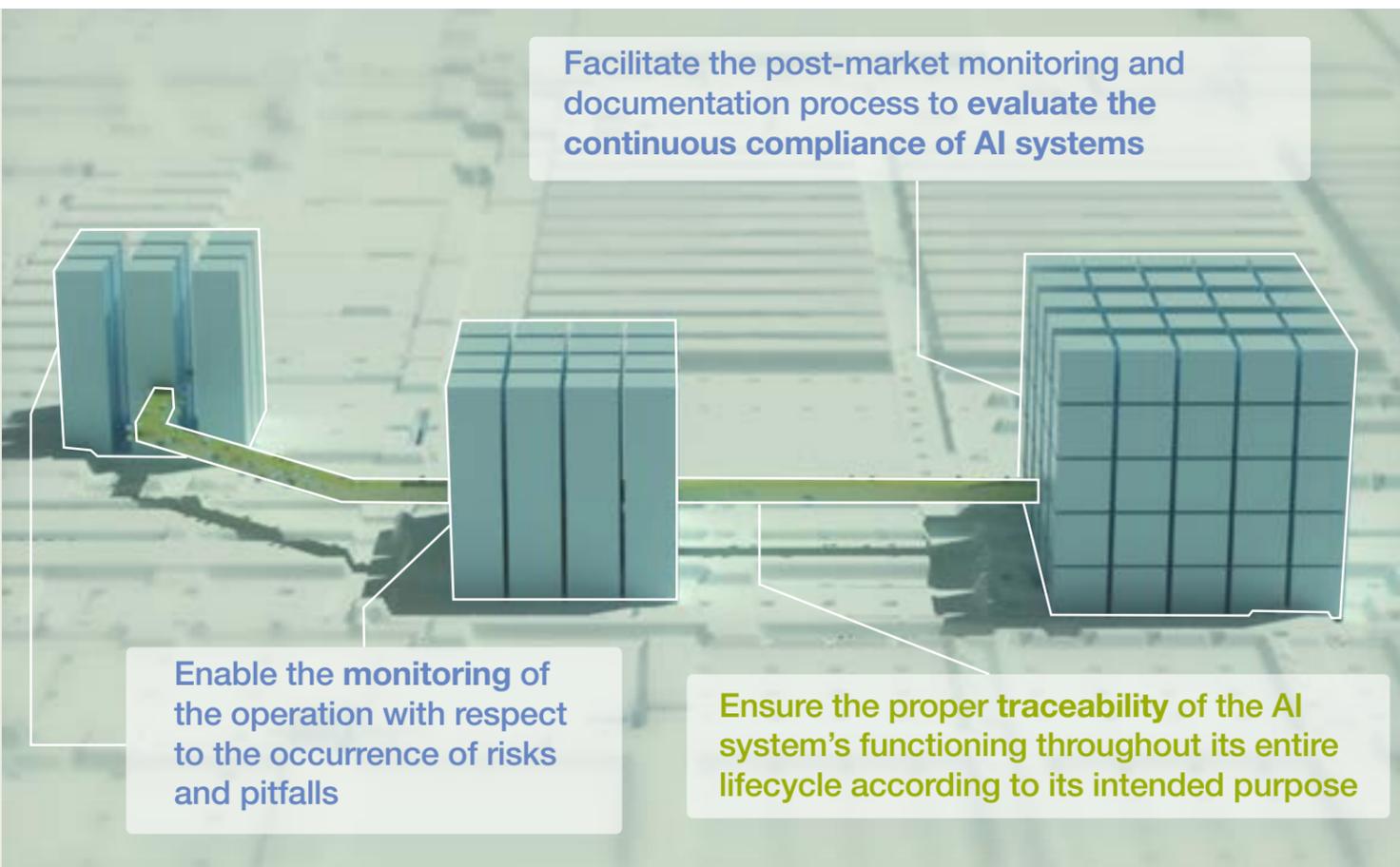
MLOPS ARCHITECTURE PLATFORM DEFINITION

GOVERNANCE

PLATFORM MODULES

Model Development

Environment Provisioning

Audits & Alerts
- Logs Management
- Functional Monitoring
- App. Perf. Management

Pipelines Management
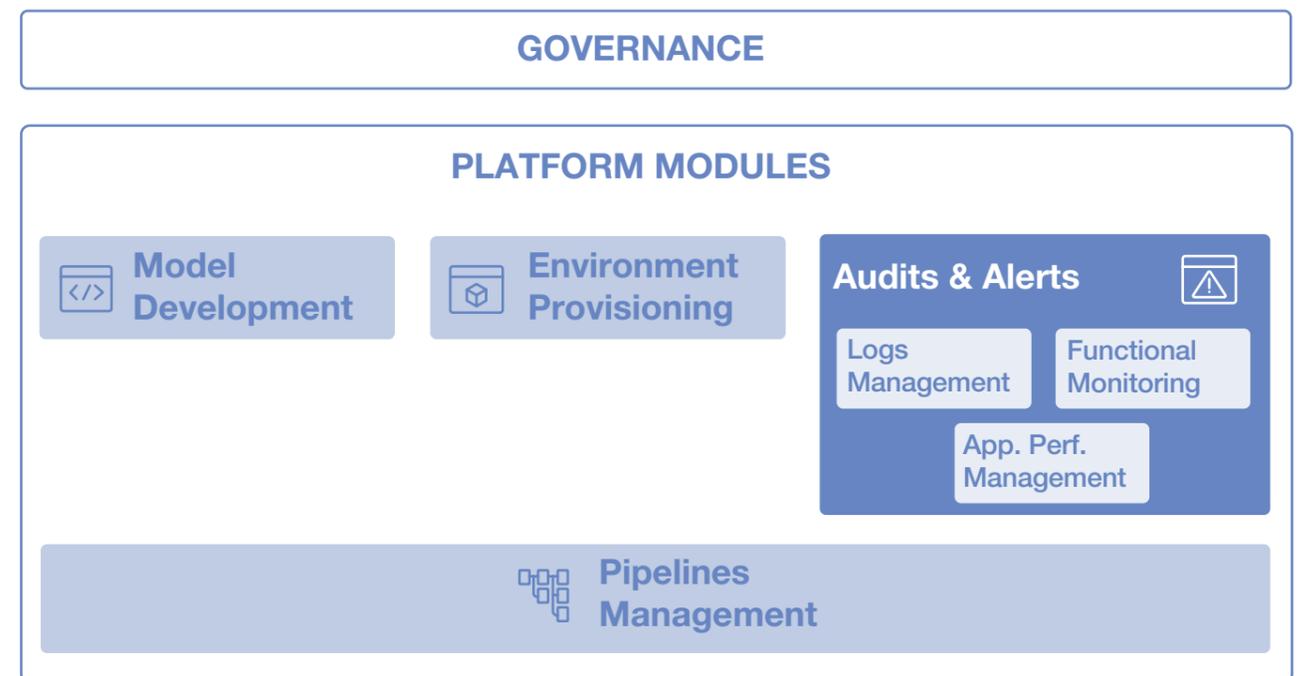
Transparency and Provisions of Information to Users

REQUIREMENT BREAKDOWN

The Regulation looks forward to guaranteeing that the AI system's operations are sufficiently transparent and explainable for both developers and users to interpret the system's output and use it appropriately.

Furthermore, to attain higher transparency levels, high-risk AI systems must attach complete instructions or manuals of use with all the relevant information to ensure the appropriate usage of the AI system.

AI SYSTEMS INSTRUCTIONS FOR USE
WHAT TO INCLUDE?

- Identity and the contact details of the provider
- Characteristics, capabilities and limitations of performance
- Description of the changes & performance

- Description of the human oversight measures
- Expected lifetime of the system
- Description of maintenance measures to ensure the proper functioning

KEY STEPS TOWARDS COMPLIANCE

Documentation about AI systems should not only target AI teams but also address the specific needs related to the interpretability by AI systems users.

This approach to transparency encompasses both explainaibility techniques (global & local) as well as a methodology to deliver the AI systems "instructions". These should be systematic and structured on a document to be applied to all AI systems developments.

As an everis AI development best practice, we've have defined a "model development manual", an internal documentation standard to be applied across all AI Lab experiments, boosting efficiencies and promoting reproducibilities of AI initiatives.

Human Oversight

REQUIREMENT BREAKDOWN

With the advances in technology, AI systems' decision-making processes are becoming increasingly autonomous, leading to little to no human intervention required along its operating lifetime.

However, the regulation urges to keep humans in the loop, not as an alternative, but as a necessity to oversee the system's operations, verify its outcomes, and intervene when necessary.

As a result, AI systems' design, development and operations must avoid causing harm to the health and safety of people, minimizing the potential risks throughout its entire lifecycle.

The Human Oversight approach to regulation:
According to the AI Regulation, the proper implementation of Human Oversight measures should lead to:
- Fully understand the capacities, limitations, and risks of the AI system
- Correctly interpret the high-risk AI system's output
- Comprehend whether to use the AI system
- Wisely interrupt the system through a "stop" button

KEY STEPS TOWARDS COMPLIANCE

Defining an AI Accountability Framework is recommended for organizations to clearly identify stakeholders' roles and responsibilities and assign adequate human-machine interface tools since the birth of the initiative.

Such structure should be scalable by nature and designed to keep in step with gains in maturity in the overall AI Teams structure.

AI ACCOUNTABILITY FRAMEWORK

AI Stakeholders

COMMUNICATE

ASSIGN

OVERSEE

Roles

Reporting Structure

EXECUTE

REPORT TO

Responsabilities
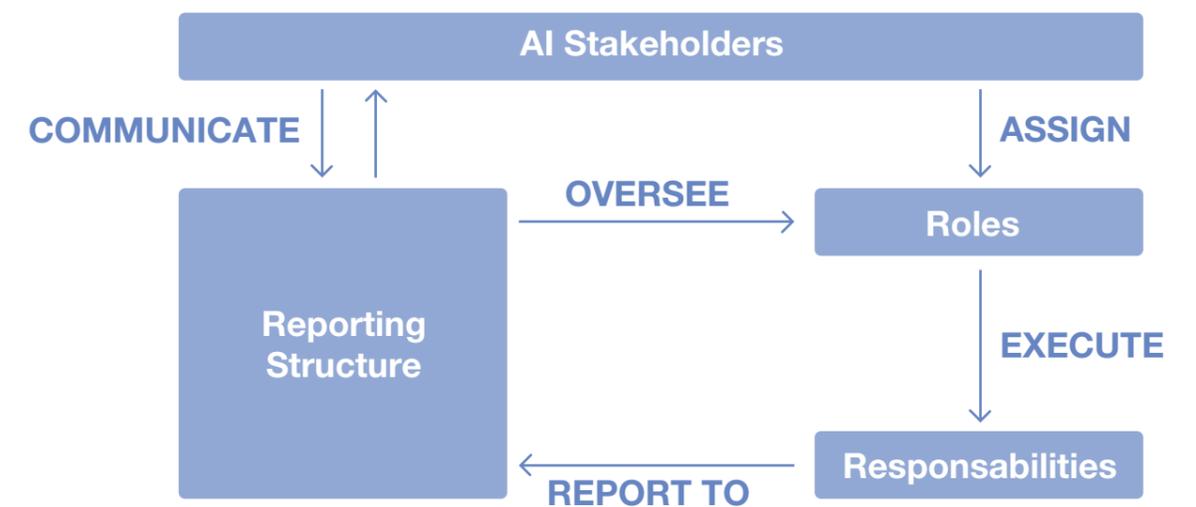
Accuracy, Robustness and Cybersecurity

REQUIREMENT BREAKDOWN

The new AI regulation looks forward to building resilient AI models that are protected against risks, inconsistencies and external vulnerabilities when running operations.

For that reason, it demands organizations and providers of high-risk AI systems to establish a homogeneous threshold by defining a set of measures and KPIs regarding accuracy, robustness and cybersecurity:

KEY STEPS TOWARDS COMPLIANCE

To reinforce quality and security standards for AI systems, organizations seeking to scale AI across production environments need to align guarantee AI lifecycle quality with **AI-to-Production Validation Tools and Methodologies** that ensure a safe and robust AI lifecycle management.

An AI-to-Production standard integrates customized metrics and processes to define a homogeneous compliance threshold.
This standard also involves solutions to prevent external threats and tools for enabling reproducibility.

TRUSTWORTHY AI MODELS

ACCURACY
Specify the relevant accuracy metrics used to overcome errors, faults, or inconsistencies that may occur across the AI Model

ROBUSTNESS
Place technical redundancy solutions:
- Backup plans   - Fail-safe plans
Place appropriate mitigation measures to avoid biased outputs due to feedback loops, that is, inaccurate outputs used as an input for future operations.

CYBERSECURITY
Place technical solutions to address vulnerabilities:
Measures to prevent and control for attacks trying to manipulate the system output ('data poisoning', adversarial examples)

AI-TO-PRODUCTION VALIDATION TOOLS & METHODOLOGIES

ACCURACY
Ensuring performance of the models deployed to prevent models staleness and biased outputs.

ROBUSTNESS
Monitoring health of the systems where the models are deployed prepared with technical redundancy mechanisms.

CYBERSECURITY
Guaranteeing security of the AI systems addressing models vulnerabilities in regards to potential manipulation or attacks.
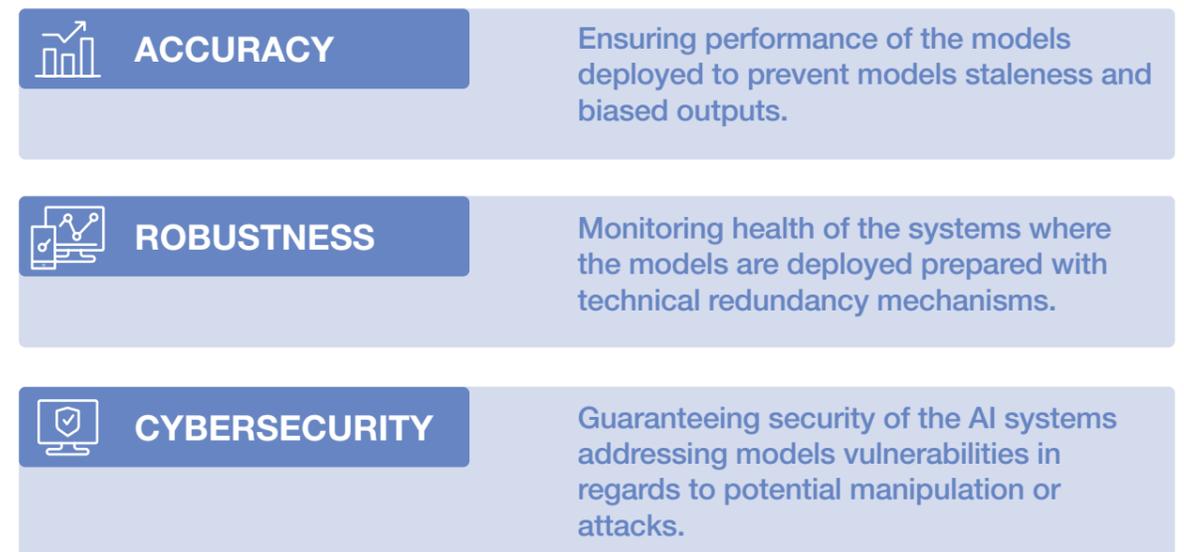
Technical Documentation
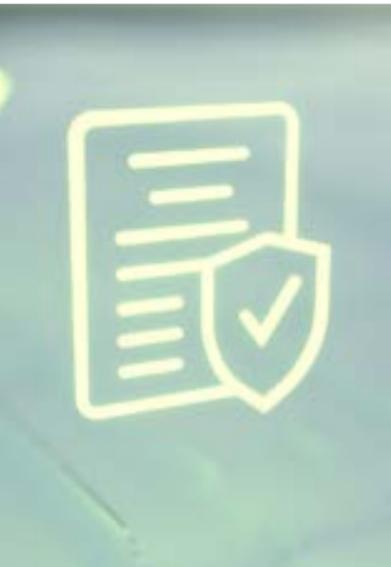
REQUIREMENT BREAKDOWN

To demonstrate high-risk AI system compliance with the mandatory requirements, the Regulation proposes to document the technical processes involved throughout the end-to-end AI systems lifecycle.

For that reason, organizations must place the technical documentation as a compass when designing and developing High-risk AI systems, supporting them to:
- Remain compliant with the mandatory requirements
- Ensure a homogeneous methodology for the proper documentation of all AI systems across the organization
- Facilitate traceability, monitoring & auditability

INFORMATION TO BE INCLUDED IN THE TECHNICAL DOCUMENTATION:

01 A general description of the HRAIS*

02 A detailed description of the elements of the AI system and of the process for its development

03 Detailed information about the monitoring, functioning and control of the AI system

04 A detailed description of the risk management system

05 A description of any change made to the system through its lifecycle

06 A list of the harmonized standards applied

07 A copy of the EU declaration of conformity

08 A description of the system performance in the post-market phase, including the post-market monitoring plan

*HRAIS: High Risk AI System

KEY STEPS TOWARDS COMPLIANCE

In order to keep track with AI systems, we guide organizations into defining a comprehensive set of information for models in production, under development or recently decommissioned, fulfilling requirements across five domains within a centralized Model Registry.

MODEL REGISTRY - DOCUMENTATION CATEGORIES

BASIC INFO
- Model Status
- Model Type
- Product Related
- Model Use Scope
- Data Sources
- Model Risk Rating
- Model Version
- Model Approval Date

STAKEHOLDERS
- Model Owner
- Model Developer
- Model Approver
- Model User
- Model Maintenance

MODEL METHODOLOGY
- Model Parameters
- Model Configuration
- Feature Pipeline
- Training Dataset
- Validation Dataset

MODEL QUALITY
- Model Impact Assessment
- Data Quality Reports
- Model Validation Reports
- Model Dependencies
- Model Infrastructure

MONITORING
- Performance KPIs
- Functional KPIs
- Alerts Defined
- Model Issues Log
- Model Adjustment Logs

A centralized model registry pursues three main objectives at an organizational-level:
- AI Democratization: Model registries facilitates sharing of expertise and knowledge across teams by making AI models more discoverable.
- Agile Innovation: generates efficiency through models reusability.
- Enhance Traceability: provides full visibility and enables governance by keeping track of each model's activity centralizing insights about "how, when, and why".

Conformity Assessment

REQUIREMENT BREAKDOWN

Organizations and providers of high-risk AI systems must verify that their AI systems successfully meet all provisions and standards, not only prior to putting it into service, but also after being distributed in the marketplace.

Thus, the Conformity Assessment is a written verification process of compliance that agrees and ensures with all the following:

01 — Comply with the harmonized standards published in Official Journal of the EU & comply with the technical documentation requirements

02 — Compliance verification with the quality management system

03 — Compliance verification with the post-market monitoring system

04 — Draw up an EU declaration of conformity

05 — Affix the CE marking of conformity

KEY STEPS TOWARDS COMPLIANCE

As established within the AI regulation proposal, aligning compliance requirements with the defined risk management system should leverage internal control mechanisms to ensure ongoing compliance.

Also, developing an internal audit procedure translates higher transparency and consistency to the internal verification methodology.

The Audit procedure definition relies on running automatic periodic verifications to examine the quality management system, as well as, the information contained in the technical documentation, smoothing the post-market monitoring processes.

A Guide to start

DEFINING THE TRUSTWORTHY AI JOURNEY

REGULATORY REQUIREMENTS WRAP UP

Risk Classification

Risk Management

Accountability Framework

Human Oversight

Data Transformation Framework for AI

Data and Data Governance

AI-to-Production Validation

Accuracy, Robustness and Cybersecurity

Audit & Alerts

Record-keeping

Model Registry

Technical Documentation

Model Development Manual

Transparency and Provision of Information to Users

Audit Procedure

Verfication of Conformity

AI Assets & Solutions   Regulation Requirement

FIRST STEPS TOWARDS A TRUSTWORTHY AI JOURNEY

HIGH-RISK AI SYSTEMS

The methodology seeks progressive compliance with upcoming regulation.

NON-HIGH-RISK AI SYSTEMS

The methodology seeks a voluntary alignment through a code of conduct and self-regulation.

AI Compliance Assessment

In depth-evaluation of compliance requirements with high-risk AI system standards.

AI Compliance Action Plan

Define the compliance roadmap and action plan of initiatives to align technical needs and capabilities.

Compliant Organization & Culture

Identify and align compliance responsibilities within the organization, fostering internal culture and change management to promote adoption of the Trustworthy AI vision.

GETTING READY FOR TRUSTWORTHY AI REGULATION

About everis NTT Data

everis is part of NTT Data, named a Challenger by Gartner in its 2020 Magic Quadrant for Data and Analytics Service Providers Worldwide.

The company shares the Innovation DNA as part of NTT Group, accelerates open ecosystems and contributes to fostering Responsible AI across its operations.

As a trusted global innovator, our values comes from "consistent belief" to shape the future society with clients and "courage to change" the world with innovative digital technologies.

For more information

To find out more about how everis NTT Data can help your business:

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