



Guide 2. Practical guide and examples to understand the AI Act

European
Artificial Intelligence Act

Companies that are beginning to know the

This guide has been developed within the framework of the development of the Spanish AI regulatory sandbox pilot, in collaboration between the participants, technical assistance, potential national competent authorities and the sandbox expert advisory group.

The guide aims to serve as an introductory support to the European Regulation on Artificial Intelligence and their applicable obligations. Although **it is not binding and does not replace or develop the applicable regulations, it provides practical recommendations** aligned with regulatory requirements pending the approval of harmonised implementing rules for all member states.

This document is subject to an **ongoing process of evaluation and review**, with periodic updates in line with the development of standards and the various guidelines published by the European Commission. This guide has been updated in accordance with the Digital Omnibus amendments to the AI Act.

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Detailed Index

1. Preamble.....	5
1.1 Purpose of the document	5
1.2 How to read this guide?	5
1.3 Who is it for?	5
2. Examples of AI Systems.....	6
2.1 AI system for biometric identification at work	6
2.2 AI System in Personnel Management – Promotion	6
2.3 AI system for predicting the risk of social exclusion and assessing access to aid/subsidies.....	7
2.4 AI System for Chronic Disease Management - Smart Insulin Pump.....	8
2.5 AI system for the detection of false reports	8
3. Definitions with examples	9
3.1 Artificial Intelligence System (AI System)	9
3.2 Placing on the market.....	10
3.3 Making available on the market	10
3.4 Intended purpose	10
3.5 Safety Component	11
3.6 Substantial modification.....	11
3.7 Post-market monitoring system.....	12
3.8 Common Specification	12
3.9 Training Data	13
3.10 Validation Data.....	13
3.11 Testing Data	13
3.12 Input Data	14
3.13 Biometric identification	14
3.14 Biometric Verification	14
3.15 Biometric categorisation system	15
3.16 Remote Biometric Identification System	15
3.17 Serious incident.....	15

3.18 Widespread infringement.....	16
3.19 Testing in real-world conditions.....	16
3.20 Real-world testing plan	16
3.21 Deep fake.....	16
3.22 General Purpose AI Model	16
3.23 Systemic Risk	17
3.24 Life cycle of an AI system	17
4. Introduction to Technical Guides.....	18
4.1 The Spanish Sandbox IA pilot.....	18
4.2 Context of publication of the technical guides	20

1. Preamble

1.1 Purpose of the document

The aim of this guide is to facilitate the understanding of the AI Act from a practical approach. To this end, an introductory context of the technical guides is provided, as well as hypothetical examples of high-risk systems and AI that are used throughout the guides with a didactic objective that helps to improve their understanding.

This guide takes as a reference Regulation 2024/1689 of the European Parliament and of the Council, of 13 June 2024 (European Regulation on Artificial Intelligence).

1.2 How to read this guide?

This guide should be read in a complementary way to the Introduction to the IA Act, in order to introduce the technical guides and help to clarify some of the most common doubts that have arisen during the participation in the Spanish Sandbox IA pilot.

The **first section** contains the preamble, where the general purpose of the guide is presented.

The **second section** provides summaries of the examples of the use cases that are used as examples throughout the technical guides to illustrate their practical application.

The **third section** contains a glossary of some of the most relevant general terms and concepts (taken from Article 3 of the RIA) to facilitate the practical understanding of the Regulation, accompanied by examples linked to the aforementioned use cases.

In the **fourth section**, it provides a context on the development of the Spanish Sandbox IA pilot, in which the technical guides emerge, as well as a relationship between the guides and the obligations of high-risk systems, in order to facilitate their consultation.

1.3 Who is it for?

To companies and individuals who wish to improve their understanding of the AI Act and plan to use or consult the technical guides.

2. Examples of AI Systems

This section presents several examples of AI systems, in the form of patterns, that have been selected for their representativeness. Throughout all the guides and documentation provided during the sandbox, these use cases will be used as a cross-cutting example, to facilitate the explanation and understanding of the different sections. All use cases presented in this section are high-risk.

2.1 AI system for biometric identification at work

Title Attendance at work	
Description	Artificial intelligence system for biometric recognition to record time and attendance at work. It has cameras (or biometric sensors) that record entry, and cameras (or biometric sensors) that record exit, without active employee participation . The system associated with each camera records entry/exit times. The intended use is to control the time worked and not the identification or verification, so in this use case, identification is not the only purpose of the system, but the control of the time worked.
Potential Deployers	Any company, to control and monitor the attendance at work of its employees.
AI Act Annex	Annex III
Aloof	1 - Biometric systems.
Subsection	a - Remote biometric identification systems.

2.2 AI System in Personnel Management - Promotion

Title Personnel Management - Promotion	
Description	This artificial intelligence system evaluates the possible promotion of employees. The system includes a series of parameters to evaluate an organization's employees and determine whether or not they should be promoted to a new position. The promotion proposal provided by the AI system influences as one of the determining factors, and not merely ancillary, in the establishment of the remuneration of the new position.

Potential Deployers	Companies for the management of promotions of their employees, if the service or personnel management is outsourced, may have those responsible for the deployment nested.
AI Act Annex	Annex III
Aloof	4 - Employment, worker management and self-employment.
Subsection	b - AI systems intended to be used to make decisions affecting terms of work-related relationships, the promotion or termination of work-related contractual relationships, to allocate tasks based on individual behaviour or personal traits or characteristics or to monitor and evaluate the performance and behaviour of persons in such relationships.

2.3 AI system for predicting the risk of social exclusion and assessing access to aid/subsidies

Title	Prediction of risk of social exclusion and assessment of access to aid/subsidies.
Description	This artificial intelligence system will collect specific data on the family unit, as well as general data on the aid requested. The artificial intelligence system establishes access to aid concession based on the set specific parameters, as well as the general parameters that predict the risk of social exclusion in the short term. In addition to access, the system establishes a range of the amount allocated. Access and the amount allocated is directly determined by the system.
Potential deployers	Public administrations to establish access and establish the amount of aid.
AI Act Annex	Annex III
Aloof	5 - Access to and enjoyment of essential private services and essential public services and benefits.
Subsection	a - AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services, as well as to grant, reduce, revoke, or reclaim such benefits and services.

2.4 AI System for Chronic Disease Management - Smart Insulin Pump

Title	Chronic Disease Management - Smart Insulin Pump
Description	Artificial intelligence system that administers insulin by monitoring the patient's condition. It monitors the patient's condition by recording parameters such as blood sugar level, activity, pulse or volume of oxygen in the blood. These values are used by the model to predict a trend and deliver insulin automatically. The system is also responsible for managing the sending of alarms to the patient and the doctor.
Potential Deployers	The person responsible for the deployment of the system would be the medical institution or hospital that provides the doctor with the system, which he or she will apply to patients.
AI Act Annex	Annex I
Aloof	To
Subsection	11 - Medical devices.

2.5 AI system for the detection of false reports

Title	Detection of false reports
Description	Artificial intelligence system used to know the probability that a complaint filed at a police station is false by taking as a reference the complaint filed by the citizen and transcribed into the system by him or the police.
Potencial Deployers	Security forces (both national and regional in each case) that manage and process complaints from citizens.
AI Act Annex	Annex III
Aloof	6 - Law enforcement.
Subsection	c - AI systems intended to be used by or on behalf of law enforcement authorities, or by Union institutions, bodies, offices or agencies, in support of law enforcement authorities to evaluate the reliability of evidence in the course of the investigation or prosecution of criminal offences.

3. Definitions with examples

This section addresses some of the general concepts and terms described in Article 3 of the most relevant Regulation. All of these terms and concepts are used throughout the development of the rest of the sandbox guides and materials.

This content is intended to serve as a first contact with the terms and serve as a reference throughout the execution of the sandbox. Most of the definitions are accompanied by **illustrative, non-binding examples** applicable to the AI system use cases described above, with the sole purpose of providing context and facilitating the understanding of the terms presented.

The definitions indicated take as a reference the version of the Regulation published by the Council of the European Union on 13 June 2024, as well as the new definitions introduced by the Digital Omnibus. Only one of these definitions is not contemplated in the Regulation, it is the concept "life cycle of an AI system", which complements the global understanding of the stages of a system.

3.1 Artificial Intelligence System (AI System)

Artificial intelligence system: a machine-based system that is designed to operate with different levels of autonomy and that can show adaptability after deployment, and that, for explicit or implicit objectives, infers from the input information it receives how to generate output results, such as predictions, content, recommendations or decisions, that can influence physical or virtual environments;

The European Commission has published guidelines that aim to clarify this definition of an AI system¹

Example - Biometric identification at work

A set formed by the cameras that captures the information and the model that performs the analysis of the data and compares it with the stored information to generate the identification and record the information of the entry or exit event and thus monitor the time worked. This example would be a high-risk AI system of those regulated in Annex III, specifically in section 1, to the extent that it operates without the employee's active participation.

1

<https://ec.europa.eu/newsroom/dae/redirection/document/118640>

Example - Chronic Disease Management - Smart Insulin Pump

Formed by the mechanism of collecting data related to the concentration of glucose in the blood which, together with other attributes stored in the patient's database (physiology of the patient, their history and activities, such as meals and physical activity), analyzes and determines the correct dose of insulin to be administered. This example would represent a high-risk AI system of those regulated in Annex I, namely it would fall within the sectoral legislation on medical devices referred to in paragraph 11 of that Annex.

3.2 Placing on the market

Placing on the market: the first placing on the Union market of an AI system or a general-purpose AI model;

Example

In the defined use cases, the placing on the Union market of the AI systems described would correspond to the first time that such a system is put into service and used, developed or imported by a natural or legal person physically present or established in the Union.

3.3 Making available on the market

Making available on the market means the supply of a general-purpose AI system or AI model for distribution or use on the Union market in the course of a commercial activity, subject to payment or free of charge.

In the defined use cases, the placing on the market of the AI systems described would correspond to the moment at which those systems are placed for distribution or use on the market within the Union, either for remuneration or free of charge. In such a way that any of its potential managers for the deployment could acquire it and launch it.

Example - Chronic Disease Management - Smart Insulin Pump

When available and the provider has been contracted by those responsible for the deployment such as hospitals to distribute to their patients.

3.4 Intended purpose

Intended purpose: the use for which an AI system is designed by a supplier, including the specific context and conditions of use, as provided by the supplier in the instructions for use, promotional and sales materials and declarations, and technical documentation.

Example – Biometric identification at work

Its intended purpose would be the identification of employees to record the time of departure and entry, by extracting biometric patterns through the entry/exit cameras and comparing them with previously registered identities. Additionally, it should be explained that this system makes a complete reading of the employee's face, and that, once this data has been identified and collected, the system will carry out a comparison work with the information stored in the database and will analyze whether the traits it has identified correspond to any of those stored in the database. Identifying the person responsible for the deployment and recording the corresponding entry or exit event.

3.5 Safety Component

Safety Component: a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property; for the purposes of this definition, a component fulfils a safety function where its intended purpose is to prevent or mitigate risks to health and safety of persons or property.

Example – Chronic Disease Management – Smart Insulin Pump

The AI system collects the data regarding the blood glucose concentration that it analyzes along with other attributes stored in the patient's database and determines the correct dose of insulin to be administered. In this context, the security of these systems is crucial since a failure of any kind can endanger the life of the person responsible for the deployment of the system. An example of a safety component is a sensor that warns of the failure of the insulin pump in case it does not operate properly or is not even operational. The system will be equipped with a large number of safety components, but all of them must clearly notify the person responsible for deploying the device of their malfunction.

3.6 Substantial modification

Substantial modification: means a change to an AI system after its introduction into the market or entry into service that was not foreseen or projected in the initial conformity assessment carried out by the provider and as a result of which the AI system's compliance with the requirements set out in Chapter III is affected; section 2, or that results in a modification of the intended purpose for which the AI system concerned has been evaluated;

In any of the use cases presented, in particular, the change of purpose or purpose of the system to another high-risk purpose will be a substantial modification. Similarly, the modification of the system that could affect compliance with the requirements of the Regulation that have previously been assessed for compliance (risk management system, data and data governance, technical documentation, event registration, transparency towards those responsible for deployment, human surveillance, accuracy, robustness and cybersecurity) will be substantial.

Example – Detection of false reports

The initial purpose of the system is to know the probability that a complaint filed at a police station is false. A substantial modification could occur in the event that the system is used in investigations to evaluate the veracity of the statements of the persons under investigation. Or that the introduction of texts of interactions on social networks is practiced to determine patterns of falsehood in these contexts.

3.7 Post-market monitoring system

Post-market monitoring system: all activities carried out by providers of AI systems aimed at collecting and reviewing the experience gained from the use of AI systems that they place on the market or put into service, in order to detect the possible need to immediately apply any type of corrective or preventive measure that may be necessary.

Example – Chronic Disease Management – Smart Insulin Pump

The system provider shall have a procedure for monitoring the product after it has been placed on the market, collecting data and information about the behaviour of the system and opinions of those responsible for the deployment that will enable it to identify, for example, possible errors in the operation of the system and correct it. This post-market monitoring will involve the notification of incidents to the market surveillance authority and substantial modifications to the artificial intelligence system.

3.8 Common Specification

Common specification means a set of technical specifications as defined in point (4) of Article 2 of Regulation (EU) No 1025/2012 which provides means to comply with certain requirements laid down under this Regulation;

In general, and following Regulation (EU) No. 1025/2012, a technical specification is a document that prescribes the technical requirements that a product, process, service or system must meet. The technical specification refers to aspects such as quality, performance, interoperability, environmental protection, health and safety, product dimensions, name, testing, test methods, packaging, marking or labelling, and conformity assessment procedures.

In the context of the Regulation, and with respect to the common specifications, it is indicated:

1. If **harmonised standards** do not exist (or where the Commission considers them insufficient), the Commission may adopt **common specifications** in relation to the **requirements of Section II of Chapter 3**.

2. When developing the **common specifications**, the Commission **shall seek** the **views of** the relevant bodies or groups of experts (established in accordance with applicable Union law at sectoral level).
3. High-risk AI systems conforming to the common specifications shall be presumed **to** be in compliance with the **requirements of Chapter 3, Section II** (to the extent that those common specifications provide for those requirements).
4. Where suppliers do not comply with the **common specifications**, they shall duly justify that they have adopted **technical solutions** at least **equivalent** to them.

Common specifications are developed by the European Commission. For example, there are common specifications in Regulation 2017/745, of 5 April, on medical devices, to implement the requirements that are required of certain medical devices.

3.9 Training Data

Training data: The data used to train an AI system by adjusting its trainable parameters.

Example - Prediction of risk of social exclusion and assessment of access to aid/subsidies

The data with which the system will be trained are the stored data associated with the different parameters, both quantitative (income level, level of education, occupation, geographical areas, etc.) and qualitative (typified reports, textual reports). That is, all the performance data - granted or not - that is selected, to develop the artificial intelligence system, as data used during its training.

3.10 Validation Data

Validation data: the data used to provide an assessment of the trained AI system and adapt its non-trainable parameters and learning process to, among other things, avoid underfitting or overfitting;

Example - Prediction of risk of social exclusion and assessment of access to aid/subsidies

Validation data are data that allow us to evaluate the system we have trained, these data also belong to the stored data associated with the different parameters, both quantitative (income level, level of training, occupation, geographical areas, etc.) and qualitative (typified reports, textual reports), it can be a subset of the data used in the training or another subset of data from that history that was not used in the training phase.

3.11 Testing Data

Testing data: the data used to provide an independent assessment of the AI system, in order to confirm the intended operation of the AI system before it is placed on the market or put into service.

Example – Prediction of risk of social exclusion and assessment of access to aid/subsidies

Test data is data that allows us to independently evaluate the trained and validated system. This dataset must be different from the one used for training and validation but sharing exactly the same nature: stored data associated with the different parameters, both quantitative (income level, level of education, occupation, geographical areas, etc.) and qualitative (typified reports, textual reports).

3.12 Input Data

Input data: the data provided to or obtained directly by an AI system from which an output result is produced;

Example – Prediction of risk of social exclusion and assessment of access to aid/subsidies

Input data is that which is entered into the system, once it has been trained, validated, tested and put into service. In the case of use, it would be all the information collected for the application process by the person responsible for the deployment, as well as reports that may be provided or requested from other entities (social protection, primary care, etc.), likewise, in the case of the public administration, the system could use as input data those that come from other sources already registered, such as data from the Treasury, Cadastre, etc.

3.13 Biometric identification

Biometric identification: the automated recognition of physical, physiological, behavioural or psychological human characteristics to determine the identity of a natural person by comparing their biometric data with the biometric data of people stored in a database.

Example – Biometric identification at work

The act of recognizing the biometric characteristics of employees, through cameras placed at the entrance of said facilities. In this context, this AI system is a biometric identification system, depending on the use it may or may not be considered high risk.

3.14 Biometric Verification

Biometric verification: the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data with previously provided biometric data.

Example – Biometric verification to authenticate an employee's identity when entering the workplace.

The automated comparison of an employee's biometric data against the reference biometric data previously provided to the company for one-to-one verification. In this

context, this AI system is a biometric verification system and is therefore not classified as high-risk.

3.15 Biometric categorisation system

Biometric categorisation system: an AI system intended to include natural persons in specific categories based on their biometric data, unless it is ancillary to another commercial service and strictly necessary for objective technical reasons.

Example

An AI system categorizes website users and potential customers based on their behaviour on it, through an analysis of the keystroke.

3.16 Remote Biometric Identification System

Remote biometric identification system: an AI system aimed at identifying natural persons without their active participation and usually remotely by comparing their biometric data with those contained in a reference database;

In other words, the AI system aims to detect several people or their behaviour simultaneously, in order to considerably simplify the identification of people without their active participation. AI systems intended for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person they claim to be, as well as the identity of a natural person for the exclusive purpose of having access to a service, unlocking a device or having security access to a premises, are excluded.

3.17 Serious incident

Serious incident: an incident or malfunction of an AI system that, directly or indirectly, has any of the following consequences:

- (a) the death of a person or serious damage to his or her health;
- (b) a serious and irreversible disruption to the management or operation of critical infrastructure;
- (c) failure to comply with obligations under Union law to protect fundamental rights;
- (d) serious damage to property or the environment;

Example - Chronic Disease Management - Smart Insulin Pump

The AI system collects data regarding blood glucose concentration and together with other attributes stored in the patient's database (patient's physiology, history, activities, such as meals and physical activity) analyzes and determines the correct dose of insulin to be administered. Expanding on the example of the definition of withdrawal of the artificial intelligence system, in this scenario, a failure in the system could result in an administration

of insulin due to excess or deficiency, if an incident were caused that causes death or serious damage to health, it would be clearly serious.

3.18 Widespread infringement

Widespread infringement: any act or omission contrary to Union law protecting the interest of individuals, which:

- a) Has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State in which:
 - i) The act or omission originated or took place;
 - ii) The provider concerned, or, where applicable, its authorised representative is located or established; or
 - iii) The deployer is established, when the infringement is committed by the deployer;
- b) Has caused, causes or is likely to cause harm to the collective interests of individuals and has common features, including the same unlawful practice or the same interest being infringed, and is occurring concurrently, committed by the same operator, in at least three Member States.

3.19 Testing in real-world conditions

Testing in real-world conditions: the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of the AI Act.

3.20 Real-world testing plan

Real-world testing plan: a document describing the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of the real-world test.

3.21 Deep fake

Deep fake: Image, audio, or video content generated or manipulated by an AI that resembles real people, objects, places, entities, or events and that may mislead a person to think that they are authentic or true.

3.22 General Purpose AI Model

General-purpose AI model: an AI model trained on a large volume of data using large-scale self-monitoring, which has a considerable degree of generality and is capable of competently performing a wide variety of different tasks, regardless of how the model is introduced to the market, and which can be integrated into a variety of downstream systems

or applications; except for AI models that are used for research, development, or prototyping activities before they are introduced to the market.

An indicative criterion for a model to be considered a general-purpose AI model is that its training compute is greater than 10^{23} FLOPs and it can generate language (whether in the form of text³ or audio⁴), text-to-image, or text-to-video².

Example

OpenAI's models such as: GPT-4, GPT-3; from Meta, the LLaMA family of models; Google's Gemini ultra or Gemini pro; from mistral: Mistral Large 2 or Mistral Small; Anthropic Claude 3 Opus or Claude 3 Haiku; among others. It must be distinguished from general-purpose AI systems, such as ChatGPT or Copilot.

3.23 Systemic Risk

Systemic risk: a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.

Requirement to be considered GPAI with systemic risk: its computational cost of training is higher than the order of $> 10^{25}$ FLOPs

3.24 Life cycle of an AI system

Life cycle of an AI system: a structured and well-defined sequence of the stages that the software goes through during its useful life, from the definition of the initial requirements (design inputs) to its retirement, including the design and development stages, validation and verification testing, deployment, operation and monitoring, continuous re-evaluation and validation.

Although this term is mentioned in the AI Act it is not explicitly defined, so the above description is merely indicative and not binding.

² See paragraphs 17 and 18 of the Commission Guidelines on the scope of the obligations for providers of general-purpose AI models established by Regulation (EU) 2024/1689 (AI Act). 19.11.2025.

4. Introduction to Technical Guides

This section provides a context for the preparation and objective of the technical guides, prepared within the framework of the Spanish AI sandbox pilot promoted by the Secretary of State for Digitalisation and Artificial Intelligence with the support of the European Commission.

The objective of the sandbox and all the materials developed and made available to the public is to help the Spanish business fabric to advance in AI regulatory compliance, providing support to companies for the commercialization of high-quality AI systems, increasing public confidence in the use of this technology.

4.1 The Spanish Sandbox IA pilot

The Spanish AI Sandbox pilot is a controlled test environment that **seeks to promote the responsible development of AI**. The objective of the pilot is to clarify the obligations laid down in the AI Act for startups and SMEs through the practical validation of the technical guidance, which is intended to serve as non-binding guidance. Through its application, the pilot seeks to generate empirical evidence and documented technical and regulatory knowledge based on the lessons learned, with a view to improving the guidance, facilitating knowledge transfer across the Spanish artificial intelligence ecosystem, and supporting the development of solutions aligned with the legal and ethical principles underpinning the AI Act, thereby fostering preparedness for the future application of the obligations laid down therein. In addition, it promotes reliable innovation, strengthens the supervisory capacity of the Spanish Agency for the Supervision of AI and allows the real impact of regulatory obligations to be assessed, contributing to European standardisation. Ultimately, it aspires to position Spain as a leader in responsible AI at a European and global level.

In November 2023, the Secretary of State for Digitalisation and AI, in close collaboration with the European Commission (DG CNECT), published Royal Decree 817/2023, which establishes the regulatory bases for the participation of companies in the AI sandbox. Subsequently, in December 2024, the official call was launched by resolution. In January 2025, the event to present the call was held.

After the evaluation of the 41 proposals submitted, 12 high-risk systems in different sectors were selected:

Illustration 1: Sandbox Participants

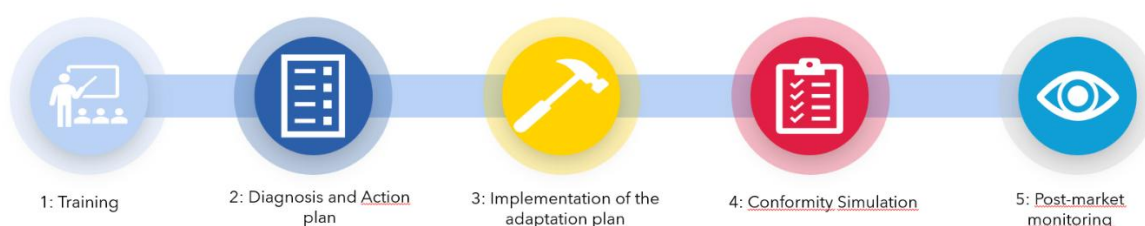
Participants

Sector	Description	System	Collaborators	Users
Access to services and assistance 	Intelligent transcription processing system for emergency communications of the Galicia 112 Operations Centre		 	
	AI system for credit scoring, creditworthiness assessment and default risk analysis of individuals based on their banking transactional data	DEDOMENA		
Biometrics 	BioSurveillance – High-performance video surveillance solution based on facial recognition (using biometric data). It is specifically designed for the simultaneous identification of individuals in crowded and highly dynamic environments			
	Veridas Age Verification – System for verifying users' age on vending machines, ensuring regulatory compliance in the sale of regulated products such as tobacco, as well as products subject to pending regulation, such as vaping products	VeriDas		
Employment 	Shakers AI Matchmaker – AI-driven matching system that uses personalised recommendations to connect freelance talent with business projects	shakers		
	Ranking of applicants via HyM (How You Match) – Assessment of suitability for the position through compatibility scoring between candidates' CVs and the requirements of job postings on InfoJob	Adevinta		  

Prior to the start of the project, technical guides had been developed, precursors of these guides, with the aim of facilitating the understanding of the European Regulation on Artificial Intelligence and the obligations applicable to high-risk systems to participants in the sandbox. **These guides are not binding or a substitute for regulations**, but offer practical recommendations aligned with regulatory requirements.

In April 2025, the **kick-off** event was held in which the working mode was presented to the selected participants with the proposed work schedule and the main milestones to be achieved. To sum up, participation is structured in five phases:

Illustration 2: Sandbox Phases



To support the development of the sandbox activities, on June 10, 2025, the **group of 40 expert advisors** was appointed by Resolution. This group is made up of independent professionals of recognized prestige and technical experience in related fields of knowledge, with present or past responsibilities in the academic and university field, in

collegiate institutions, associations of other types, or in the business sector. Its objective is to provide technical knowledge, support participants from their experience and prepare training material that can be used by Spanish companies in their regulatory adaptation initiatives.

4.2 Context of publication of the technical guides

The technical guides prepared within the framework of the Spanish AI Sandbox pilot have been developed thanks to the collaboration between the Secretary of State for Digitalisation and Artificial Intelligence as the promoter of the initiative and different actors: the participants, technical assistance, the group of expert advisors and various potential national competent authorities of the Regulation.

During their preparation and use, it has been observed that, during the process of developing common standards and specifications of the AI Act, **they are helping the participating companies to advance in their initiatives aimed at ensuring future regulatory compliance, as well as improving their internal quality and safety systems** in the development of AI.

That is why it has been estimated that the publication of this material could be of tremendous use to the Spanish business fabric, especially for SMEs and start-ups. As indicated on the back cover of each guide, **the guides are not binding and do not replace or develop the applicable regulations**, they simply **provide practical recommendations aligned with regulatory requirements pending the approval of harmonised rules of application for all member states**.

Below is a summary of the obligations and roles set out in the AI Act for providers and deployment managers that are covered in the technical guides:

Operator	Obligation	IA Act	Associated guide
HRIA Provider	Compliance with requirements section 2 of the Regulation	Art 16.a	15. Technical Documentation Guide 11. Cybersecurity Guide 7. Data and Data Governance Guide 5. Risk Management Guide 9. Accuracy Guide

			10. Robustness Guide 8. Transparency Guide 6. Human Oversight Guide
HRIA Provider	Have a quality management system in place	Art 16.c	4. Quality Management Guide
HRIA Provider	Retain log files automatically generated by your systems	Art 16.e	12. Records Guide
HRIA Provider	Conformity assessment procedure	Art 16.f	3. Conformity assessment guide
HRIA Provider	Take necessary corrective action	Art 16.j	14. Serious Incident Reporting Guide
HRAI Providers	Incident Reporting	Art 73	14. Serious Incident Reporting Guide

Operator	Obligation	IA Act	Associated guide
HRIA Deployment Manager	Assign human oversight of the system to individuals with the necessary competence, training, and authority.	Art 26.2	6. Human Oversight Guide
HRIA Deployment Manager	Retain log files automatically generated by your systems	Art 26.6	12. Records Guide
HRIA Deployment Manager	Inform the supplier or distributor if they believe that the use	Art 26.5	14. Serious Incident Reporting Guide



	of the system in accordance with their instructions may result in a risk to health, safety or fundamental rights; Error! Marcador no definido. , and suspend the use of the system if applicable		
HRIA Deployment Manager	Inform the supplier or distributor, the importer and the market surveillance authority of serious incidents.	Art 26.5	14. Serious Incident Reporting Guide



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