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# The European Union Artificial Intelligence Act

*Value Chain Creation*

*August 2024*

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## — Providing you with an insight on the AI risk landscape

We are pleased to present the EU AI Act Value Chain.

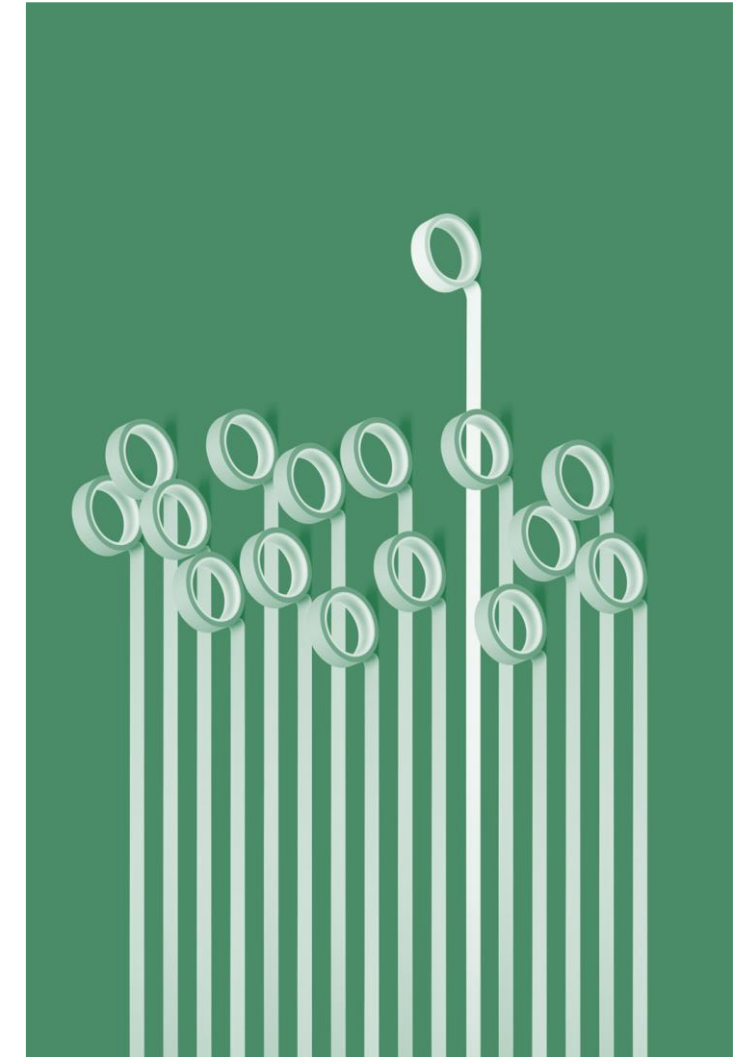
AI systems are those which require input and support from multiple parties. They are acknowledged as a highly complex, evolving family of technologies that have general purpose application, according to the EU AI Act. In this sense, they affect multiple segments of the economy given both their availability and application.

The Value Chain (see **Slide 6**) is a representation of the different parties involved across the AI system lifecycle (see **Slide 5**), in the context of the EU AI Act. This builds on the definition offered by **CEPS** which is “organisational process through which an individual AI system is developed and then put into use (or deployed). Proactively considering which organisations may execute on which parts of the AI value chain is necessary to ascertain which organisation is best placed to conform with regulatory requirements, and more generally to ensure safe and responsible function of the AI system.” This document aims to provide a comprehensive view of all actors in the AI value chain following the EU AI Act’s entry into force on 1<sup>st</sup> August 2024 and are based on the expert opinion of specialists and market practitioners at AI & Partners leveraging over 3.5 years of experience.

These indicative scenarios have been constructed in line with reference to the EU AI Act.

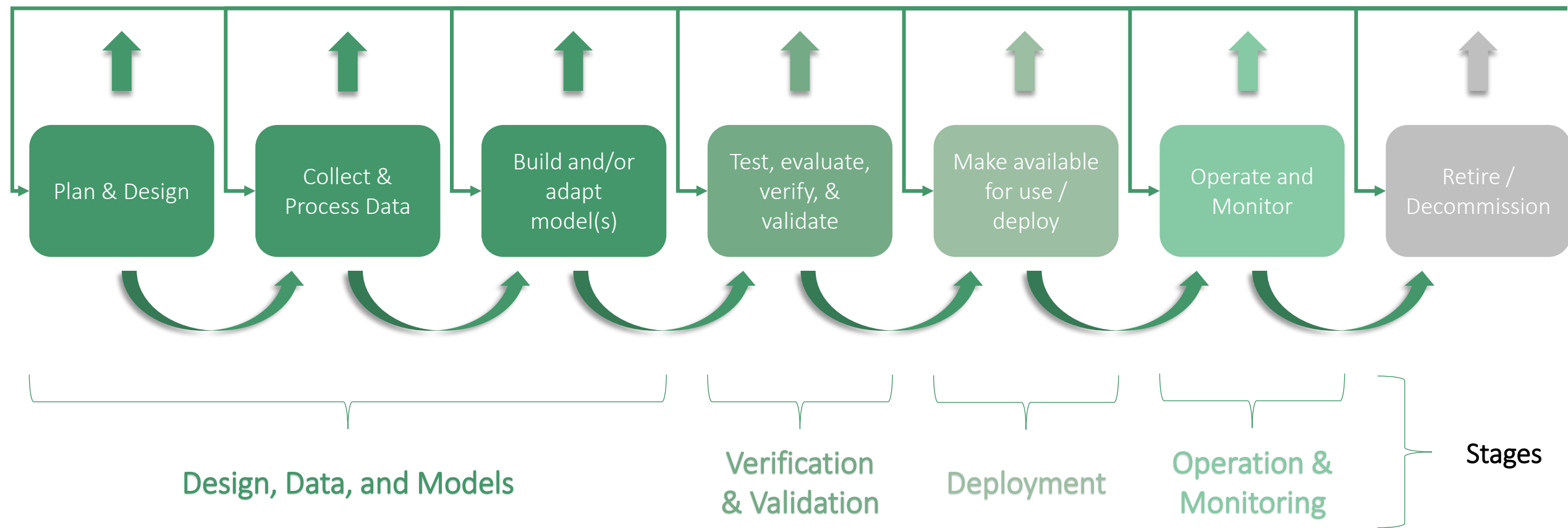
All scenarios have been designed and created as part of brainstorming sessions together with extensive market research. All references to the EU AI Act relate to the version dated [13 June 2024](#).

We hope you find the report useful and welcome your comments and feedback.



— Covering full lifespan of an AI system

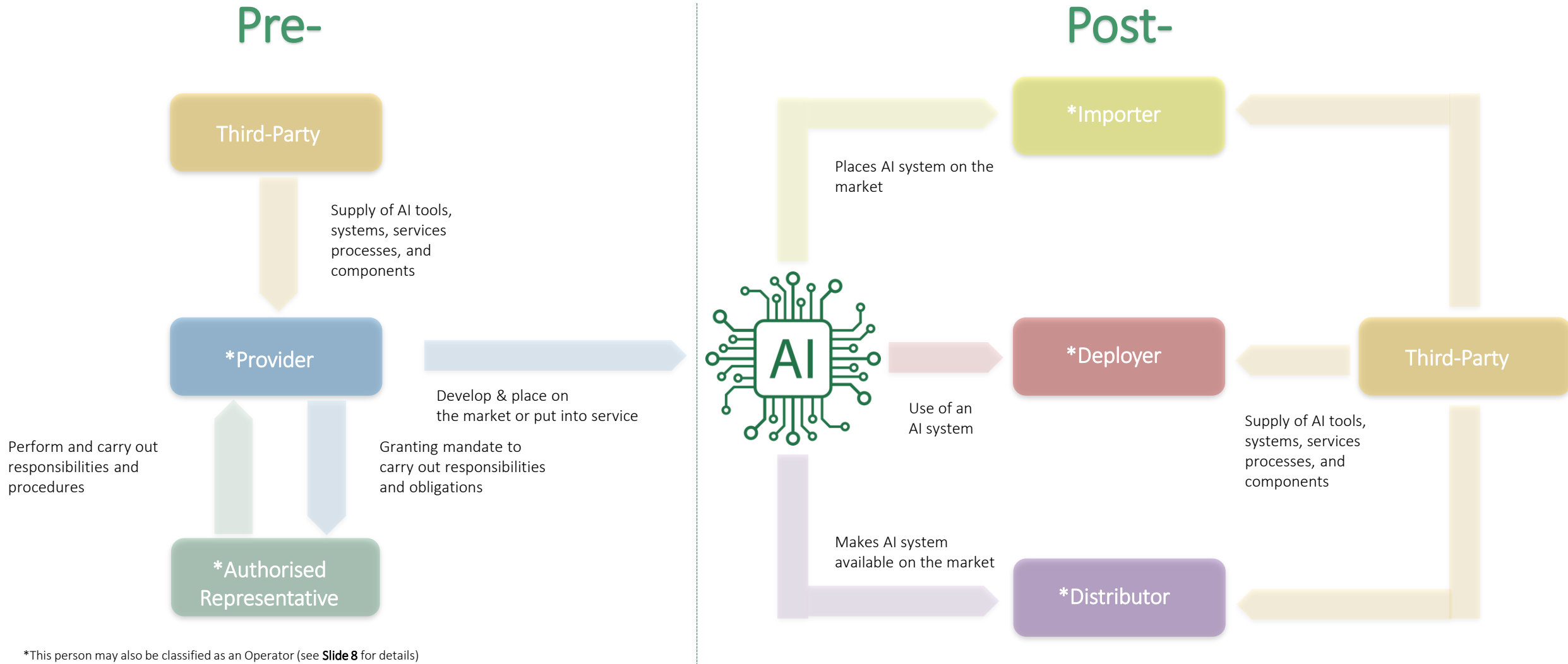
# AI System Lifecycle



# — Encompassing risks and guardrails with varying safety benefits and challenges at each stage

Stage	Sub-Stage	Definition	Reference(s)
Design, Data, and Models	Plan & Design	<p>This stage involves the initial conceptualization and planning of the AI system. It includes:</p> <ul style="list-style-type: none"> <li><b>Design Specifications:</b> Outlining the general logic of the AI system, including the algorithms, key design choices, and the rationale behind them. It also includes assumptions made regarding the intended users and the system's optimization goals.</li> <li><b>System Architecture:</b> A detailed explanation of how software components interact and integrate within the overall system. This includes the computational resources required for development, training, testing, and validation.</li> <li><b>Regulatory Compliance Strategy:</b> Establishing a strategy to ensure compliance with relevant regulations, including conformity assessment procedures and management of modifications.</li> </ul>	Annex IV & Article 17
	Collect & Process Data	<p>This phase focuses on gathering and preparing the data necessary for training, validating, and testing the AI model. Key activities include:</p> <ul style="list-style-type: none"> <li><b>Data Collection:</b> Gathering data from various sources, ensuring it meets the quality criteria for the intended purpose of the AI system. This includes understanding the origin of the data and the processes used for its collection.</li> <li><b>Data Preparation:</b> Involves data cleaning, annotation, labelling, updating, enrichment, and aggregation. It also includes formulating assumptions about what the data represents and assessing its availability, quantity, and suitability.</li> <li><b>Bias Detection and Mitigation:</b> Identifying and addressing potential biases in the data that could affect the system's performance or lead to discrimination. This includes implementing measures to detect, prevent, and mitigate these biases.</li> </ul>	Article 10
	Build and/or adapt model(s)	<p>This stage involves the actual development and refinement of the AI model. It includes:</p> <ul style="list-style-type: none"> <li><b>Model Training:</b> Using the prepared data to train the AI model. This involves selecting appropriate training methodologies and techniques, and understanding the computational resources required, such as the number of floating-point operations and training time.</li> <li><b>Model Evaluation:</b> Conducting evaluations to assess the model's performance, including adversarial testing to identify and mitigate systemic risks. This also involves documenting the evaluation results and any adaptations made to the model.</li> <li><b>Model Adaptation:</b> Fine-tuning and aligning the model based on evaluation results and feedback. This may include updating the model to improve its performance or to comply with new regulatory requirements.</li> </ul>	Annex XI & Article 55
Verification and Validation	Test, evaluate, verify, & validate	<p>Verification and validation are processes used to ensure that an AI system meets its design specifications and intended purpose. Key activities include:</p> <ul style="list-style-type: none"> <li><b>Verification:</b> Techniques, procedures, and systematic actions to check that the AI system's design and development meet the specified requirements. It includes design control and design verification.</li> <li><b>Validation:</b> Examination, testing, and validation procedures carried out before, during, and after the development of the AI system. It ensures that the system performs as intended in real-world conditions.</li> </ul>	Annex IV & Article 17
Deployment	Make available for use / deploy	<p>Deployment refers to the process of making the AI system available for use by the deployer or end-users. Key activities include:</p> <ul style="list-style-type: none"> <li><b>Make Available for Use/Deploy:</b> The supply of the AI system for first use directly to the deployer or for own use in the Union for its intended purpose. It includes ensuring that the system is registered and complies with all regulatory requirements before being put into service.</li> </ul>	Article 3 & 26
Operation and Monitoring	Operate and Monitor	<p>Operation and monitoring involve the continuous use and oversight of the AI system to ensure it functions correctly and safely over its lifecycle. Key activities include:</p> <ul style="list-style-type: none"> <li><b>Operate and Monitor:</b> Implementation and maintenance of a post-market monitoring system to collect and review experience gained from the use of the AI system. It involves identifying any need for corrective or preventive actions.</li> <li><b>Test, Evaluate, Verify, &amp; Validate:</b> During operation, the system must be regularly tested and evaluated to ensure it continues to meet the required standards of accuracy, robustness, and cybersecurity. This includes monitoring for any risks to health, safety, or fundamental rights.</li> </ul>	Articles 3, 10, 15 & 17

— Multi-stakeholder involvement across deployment stages



\*This person may also be classified as an Operator (see Slide 8 for details)

## — ‘Value ChAIN reaction’

### Provider

A natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge.

### Operator

A provider, product manufacturer, deployer, authorised representative, importer or distributor.

### Deployer

A natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity.

### \*Third-Party

A person that supplies AI systems, tools and services but also components or processes that are incorporated by the provider into the AI system with various objectives, including the model training, model retraining, model testing and evaluation, integration into software, or other aspects of model development.

### Authorised Representative

A natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures.

### Distributor

A natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market.

### Importer

A natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established in a third country.

\*This term is not expressly defined under Article 3. This definition has been inferred from the provisions of Recitals 88 & 89.



# Design, Data, and Models



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## Scenario

A provider is designing an AI system to improve customer service chatbots. They internally plan and design the system, specifying the requirements and desired features.

## Obligations

**Technical Documentation:** The provider must maintain detailed technical documentation, including design specifications, system architecture, and key design choices.

**Quality Management:** Implement a quality management system to ensure compliance with regulatory requirements.

**Risk Management:** Conduct a risk assessment to identify and mitigate potential risks associated with the AI system.

## Example

A company designing a chatbot must document the design process, including the rationale behind design choices and the system's architecture.



## Scenario

A provider collaborates with a third party that supplies specialized natural language processing (NLP) tools. The provider plans the design of the AI system, integrating the NLP tools provided by the third party.

## Obligations

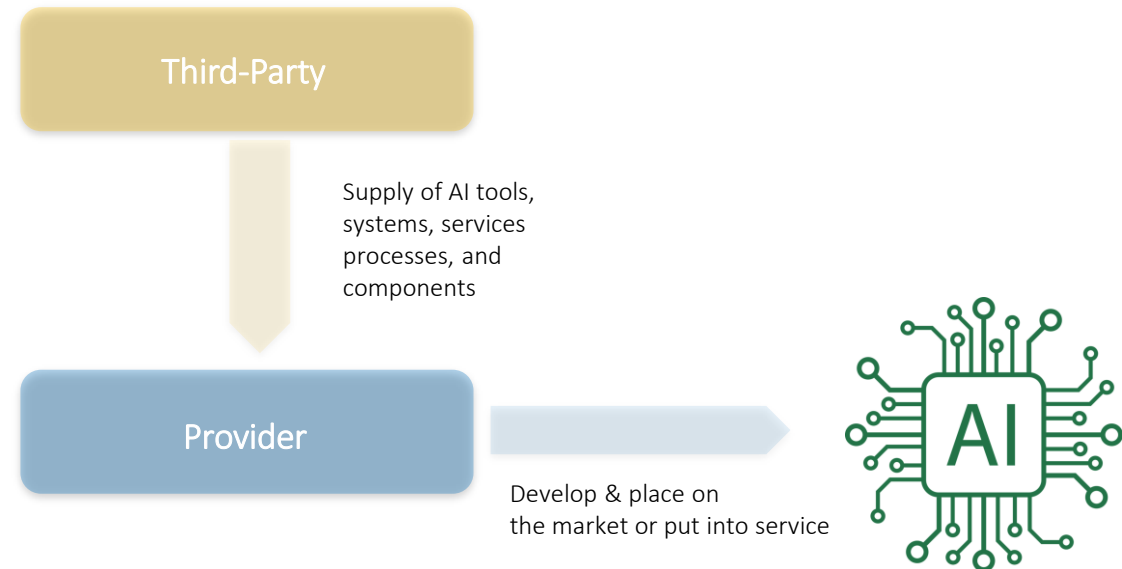
**Collaboration Documentation:** Both entities must document their roles and responsibilities, ensuring the integration of NLP tools meets regulatory standards.

**Data Governance:** Ensure data used for training and validation is of high quality and free from biases.

**Compliance Verification:** The provider must verify that the third-party tools comply with the EU AI Act requirements.

## Example

A provider working with an NLP tool supplier must ensure the tools are integrated correctly and comply with data governance standards.



# Scenario

A provider, third-party NLP tool supplier, and an authorized representative work together. The provider plans the system design, the third party provides necessary NLP components, and the authorized representative ensures compliance with regulatory requirements in the EU.

# Obligations

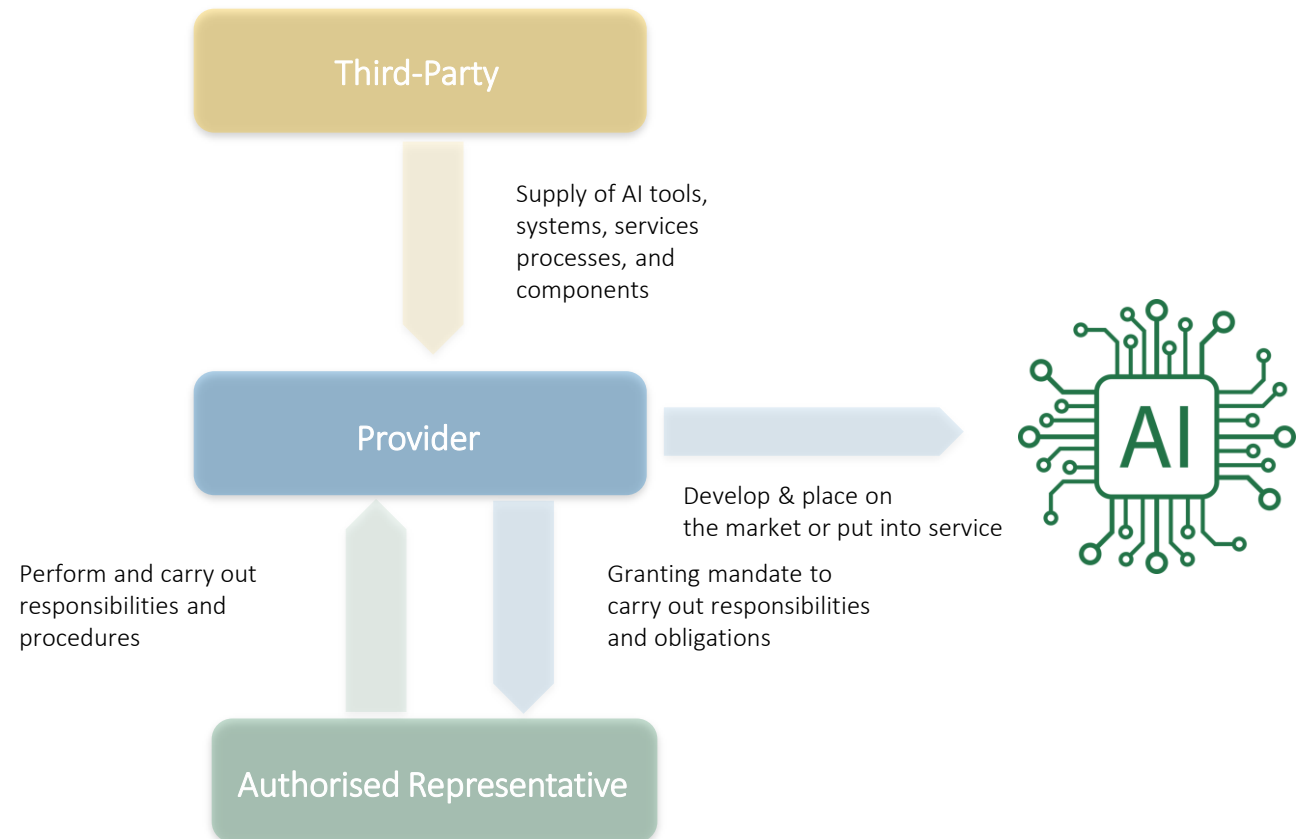
**Regulatory Compliance:** The authorized representative must ensure the entire system complies with EU regulations.

**Documentation and Reporting:** Maintain comprehensive documentation and report compliance status to the AI Office.

**Quality and Risk Management:** Implement quality and risk management systems to ensure the AI system's safety and reliability.

# Example

A provider, NLP supplier, and authorized representative must collaborate to ensure the AI system meets all regulatory requirements and is properly documented.



## Scenario

A deployer uses internal data from their customer interactions to train an AI model that predicts customer satisfaction.

## Obligations

**Data Quality:** Ensure the data used for training is relevant, representative, and free of errors.

**Data Governance:** Implement data governance practices to manage data collection, preparation, and processing.

## Example

A company using customer interaction data must ensure the data is clean, representative, and properly governed.



## Scenario

A provider collects data from a third-party data supplier to process and train an AI model. The third-party supplier provides pre-labeled datasets relevant to the provider's AI system.

## Obligations

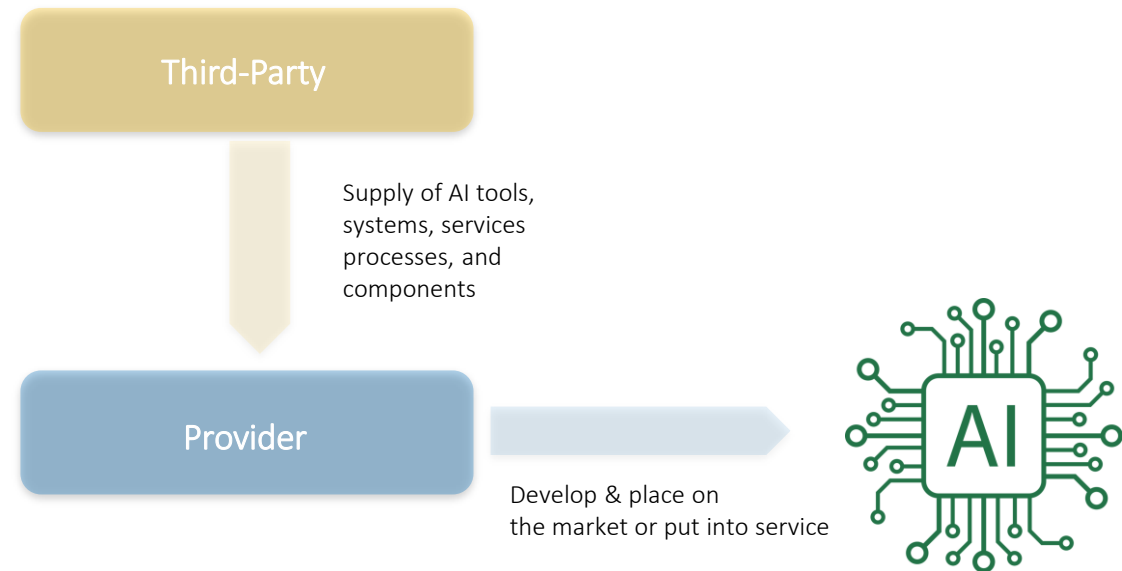
**Data Documentation:** Both entities must document the data collection and processing methods.

**Bias Mitigation:** Assess and mitigate potential biases in the data.

**Compliance Verification:** The provider must ensure the third-party data supplier complies with data governance standards.

## Example

A provider working with a data supplier must ensure the data is properly labeled, documented, and free from biases.



## Scenario

A provider, third-party data supplier, and importer collaborate. The third-party supplies data, the provider processes the data and trains the model, and the importer prepares to market the AI system in the EU.

## Obligations

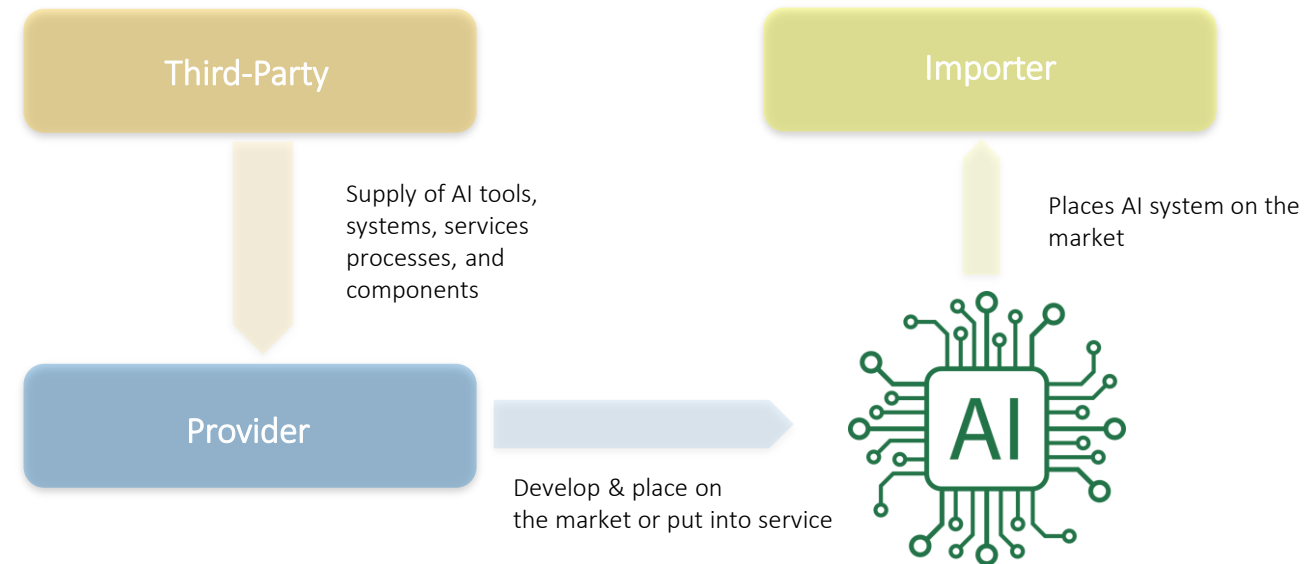
**Data Quality and Governance:** Ensure data quality and implement governance practices.

**Documentation and Reporting:** Maintain detailed documentation and report compliance to the AI Office.

**Regulatory Compliance:** The importer must ensure the AI system complies with EU regulations before marketing.

## Example

A provider, data supplier, and importer must collaborate to ensure the data is high quality, properly documented, and the AI system complies with EU regulations.



## — Build and/or Adapt Model(s)

# Scenario

A provider develops an AI model for image recognition using open-source algorithms and adapts it to recognize specific patterns relevant to their business.

# Obligations

**Technical Documentation:** Maintain detailed documentation of the model development and adaptation process.

**Quality Management:** Implement a quality management system to ensure the model meets regulatory standards.

# Example

A company adapting an open-source algorithm must document the adaptation process and ensure the model meets quality standards.





## — Build and/or Adapt Model(s)

# Scenario

A provider works with a third party specializing in model adaptation to fine-tune a pre-existing general-purpose AI model for a specific industrial application.

# Obligations

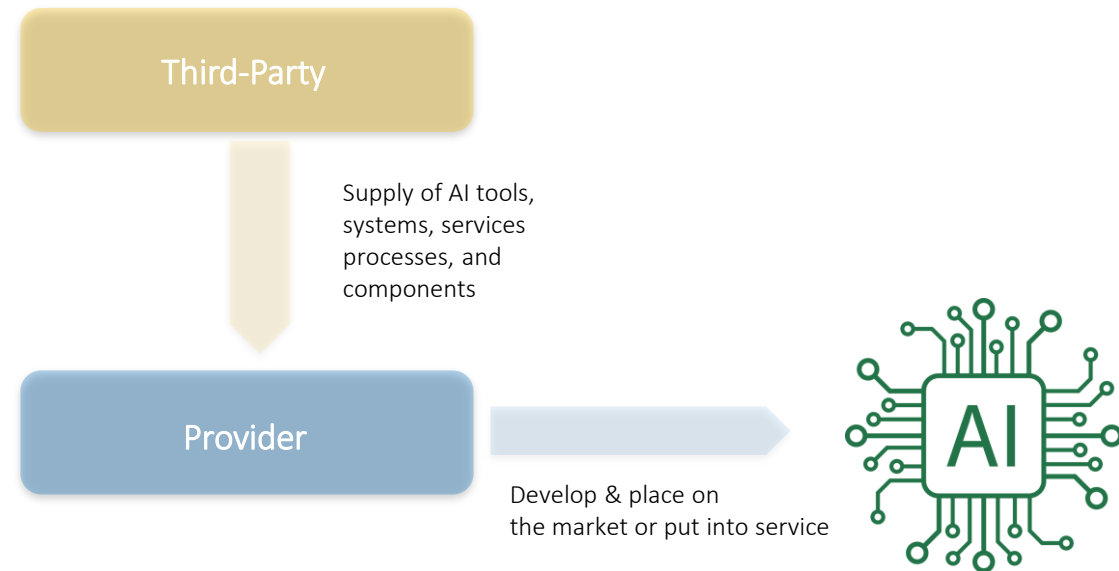
**Collaboration Documentation:** Document the roles and responsibilities of both entities.

**Compliance Verification:** Ensure the adapted model complies with EU AI Act requirements.

**Risk Management:** Conduct a risk assessment to identify and mitigate potential risks.

# Example

A provider and model adaptation specialist must ensure the adapted model is properly documented and complies with regulatory standards.



## — Build and/or Adapt Model(s)

# Scenario

A provider, third-party model adaptation service, and an authorized representative are involved. The provider builds the initial model, the third party adapts it, and the authorized representative ensures that the adaptation meets EU regulatory standards.

# Obligations

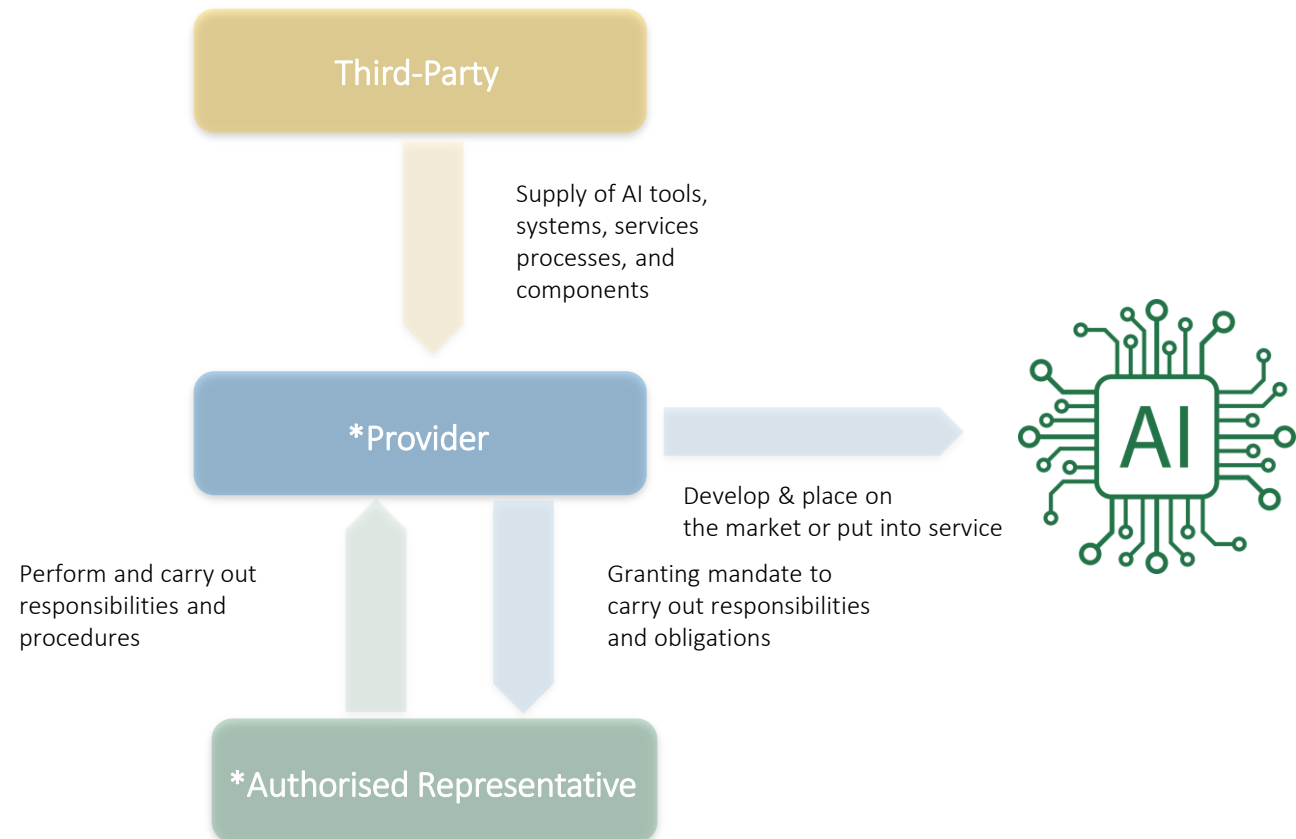
**Regulatory Compliance:** The authorized representative must ensure the adapted model complies with EU regulations.

**Documentation and Reporting:** Maintain comprehensive documentation and report compliance status to the AI Office.

**Quality and Risk Management:** Implement quality and risk management systems to ensure the model's safety and reliability.

# Example

A provider, model adaptation service, and authorized representative must collaborate to ensure the adapted model meets all regulatory requirements and is properly documented.



# Verification and Validation



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## Scenario

A deployer tests an AI system internally to ensure it meets performance benchmarks and compliance requirements before deployment.

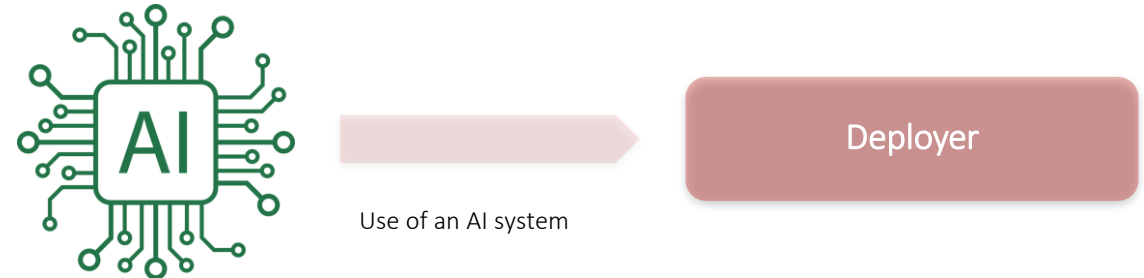
## Obligations

**Testing and Validation:** Conduct thorough testing and validation to ensure the AI system meets performance and compliance standards.

**Documentation:** Maintain detailed records of the testing and validation process.

## Example

A company testing an AI system must document the testing process and ensure the system meets performance benchmarks.



## Scenario

A provider collaborates with a third-party testing service to independently verify and validate the AI model's performance, ensuring it meets the required safety and efficacy standards.

## Obligations

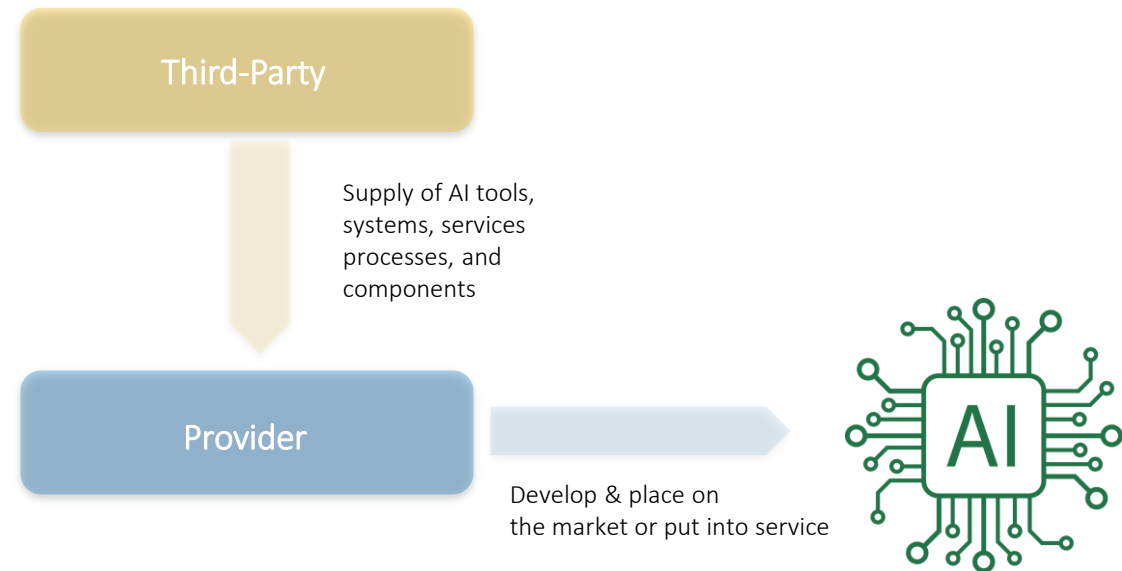
**Independent Verification:** The third-party testing service must conduct independent verification and validation.

**Compliance Documentation:** Both entities must document the verification and validation process.

**Risk Management:** Address any identified risks during the testing process.

## Example

A provider and third-party testing service must ensure the AI model is independently verified and validated, with proper documentation.



## Scenario

A provider, third-party testing service, and distributor work together. The provider develops the system, the third-party conducts verification tests, and the distributor prepares to distribute the validated AI system in the market.

## Obligations

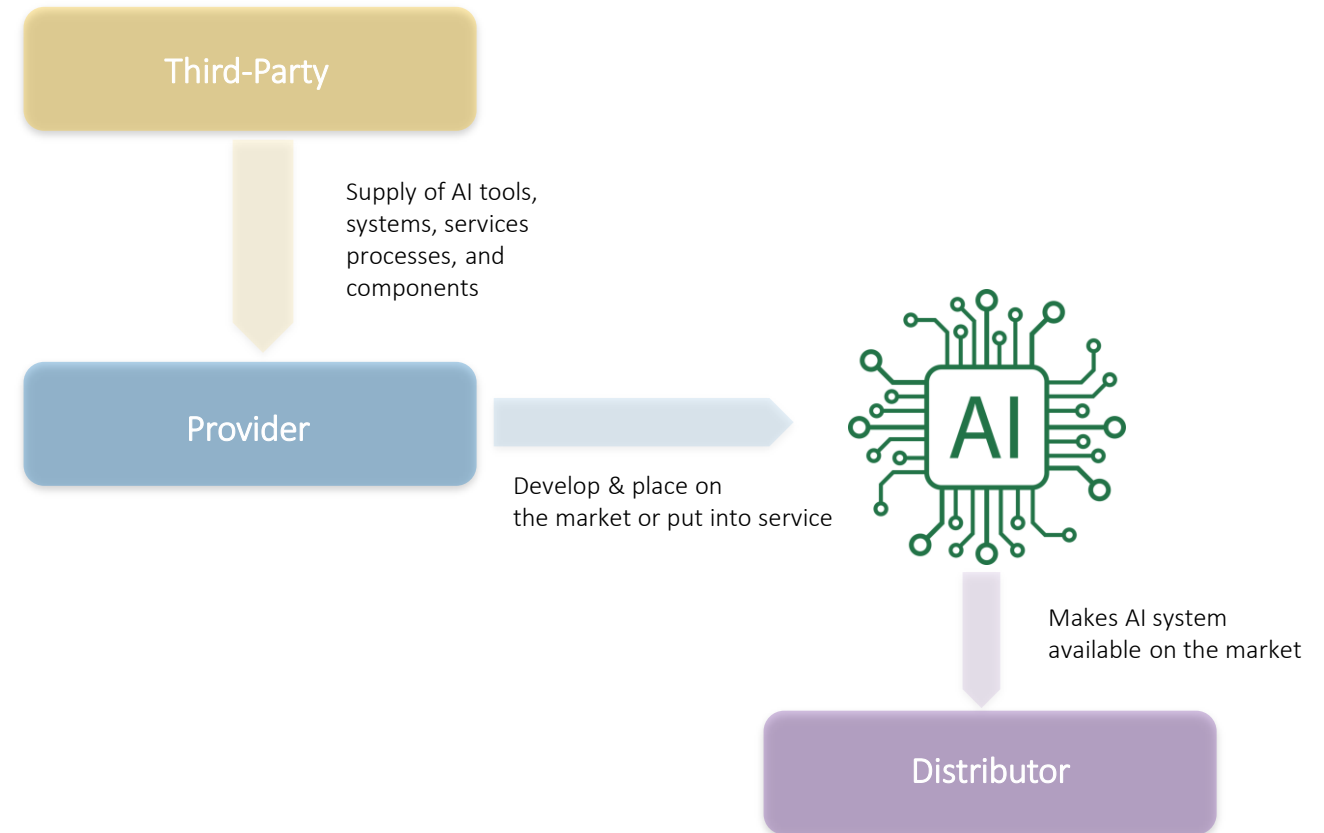
**Comprehensive Testing:** The third-party testing service must conduct thorough verification and validation.

**Documentation and Reporting:** Maintain detailed documentation and report compliance status to the AI Office.

**Regulatory Compliance:** The distributor must ensure the validated AI system complies with EU regulations before distribution.

## Example

A provider, testing service, and distributor must collaborate to ensure the AI system is thoroughly tested, validated, and compliant with EU regulations.



# Deployment



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## Scenario

A deployer deploys an AI-based recommendation system for its e-commerce platform, making it available to users directly.

## Obligations

**Technical and Organizational Measures:** Ensure the AI system is used as intended.

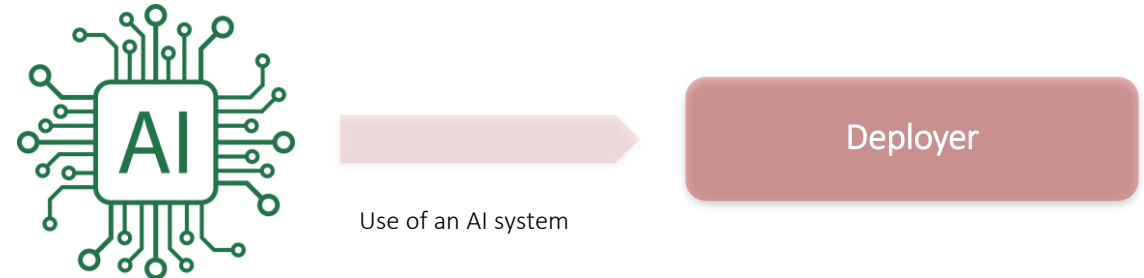
**Human Oversight:** Assign competent individuals to oversee the system.

**Monitoring and Reporting:** Monitor the system's operation and report any risks or incidents.

**User Information:** Inform users that they are interacting with an AI system.

## Example

An e-commerce platform deploys an AI-based recommendation system to suggest products to users. The platform must ensure the system operates correctly, assign staff to oversee its functioning, monitor its performance, and inform users that recommendations are AI-generated.





## Scenario

A provider completes the development of an AI system and hands it over to a deployer who integrates it into their platform and makes it available to users.

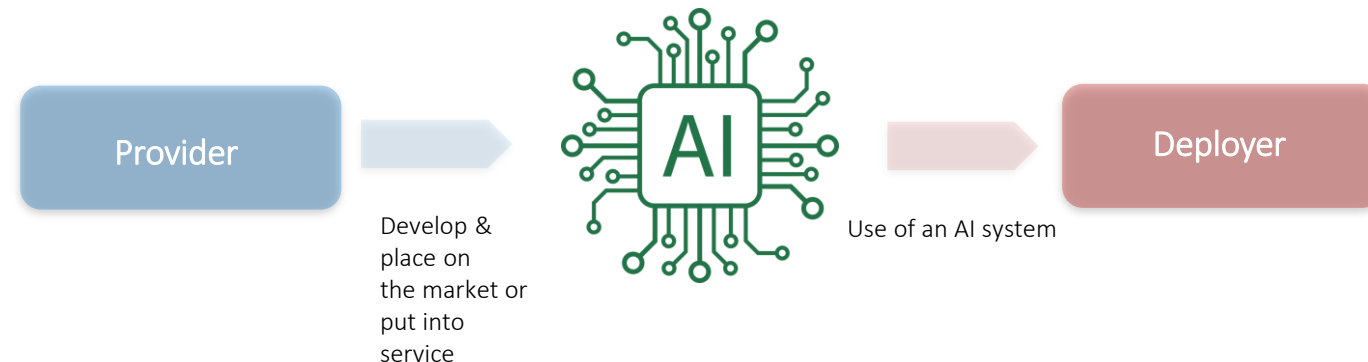
## Obligations

**Provider's Role:** The provider develops the AI system and ensures it complies with the necessary requirements, including transparency, risk management, and quality management systems.

**Deployer's Role:** The deployer integrates the AI system into their platform and makes it available to users. They must follow the same obligations as in the one-entity scenario, ensuring the system is used correctly and informing users about the AI system.

## Example

A tech company develops an AI chatbot and provides it to a customer service platform. The platform integrates the chatbot and ensures it operates correctly, assigns oversight, monitors performance, and informs users that they are interacting with an AI system.



## Scenario

A provider, importer, and deployer collaborate. The provider finishes the system, the importer ensures it complies with EU regulations and imports it, and the deployer integrates it into their service platform.

## Obligations

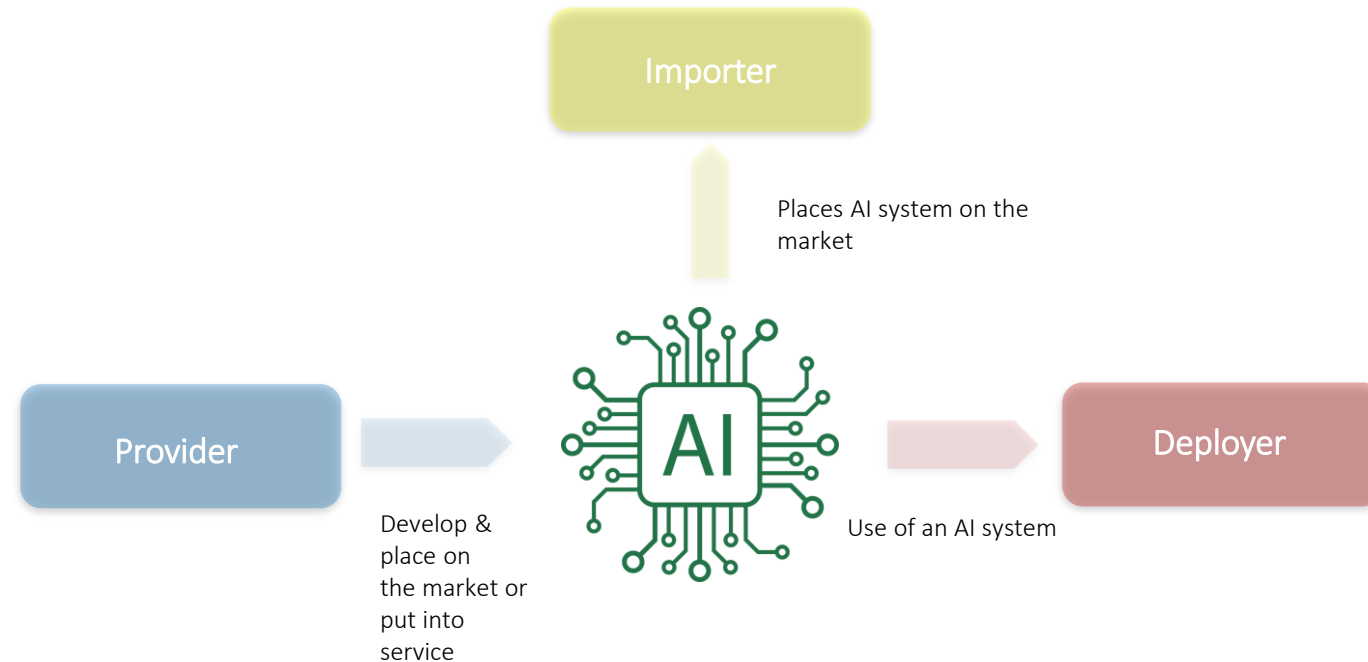
**Provider's Role:** Develops the AI system and ensures compliance with all relevant requirements.

**Importer's Role:** Ensures the AI system complies with EU regulations before placing it on the market. They must verify that the system bears the required CE marking and is accompanied by the necessary documentation.

**Deployer's Role:** Integrates the AI system into their platform and makes it available to users, adhering to the same obligations as in the previous scenarios.

## Example

A U.S. company develops an AI-based medical diagnostic tool. A European importer ensures it meets EU standards and imports it. A hospital then deploys the tool, ensuring it operates correctly, assigns oversight, monitors performance, and informs patients that an AI system is being used.



# Operation and Monitoring



## Scenario

A deployer operates and continuously monitors an AI system used for credit scoring to ensure it remains compliant with regulations and performs as expected.

## Obligations

**Technical and Organizational Measures:** Ensure the AI system is used as intended.

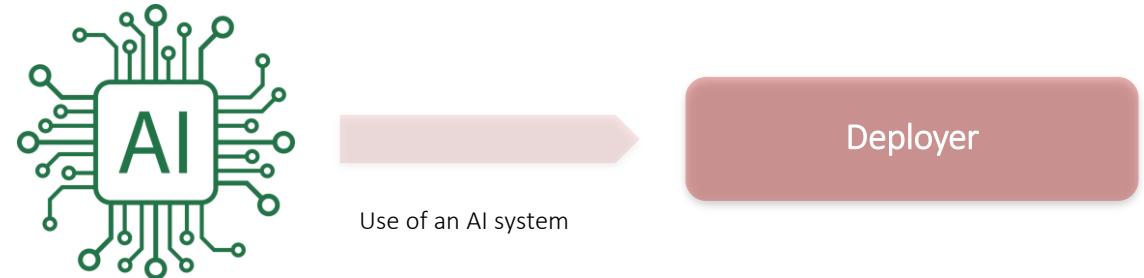
**Human Oversight:** Assign competent individuals to oversee the system.

**Monitoring and Reporting:** Continuously monitor the system's operation and report any risks or incidents.

**User Information:** Inform users that they are interacting with an AI system.

## Example

A bank uses an AI system for credit scoring. The bank must ensure the system operates correctly, assign staff to oversee its functioning, continuously monitor its performance, and inform customers that their credit scores are AI-generated.



## Scenario

A deployer operates an AI system while a third-party service provider monitors the system's performance, providing regular reports and alerting the deployer to potential issues.

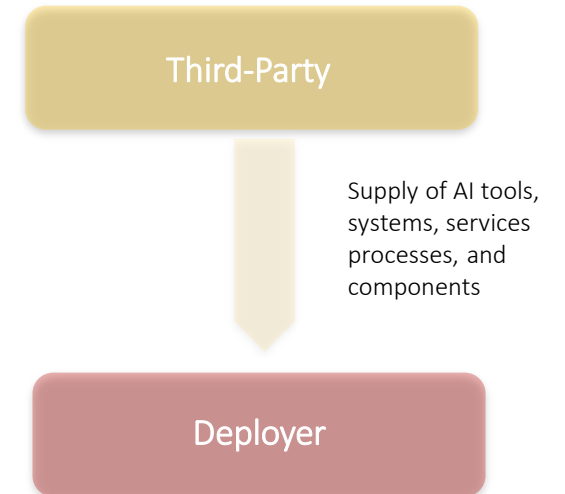
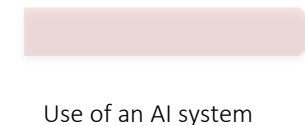
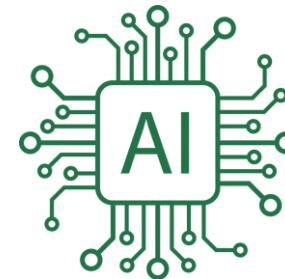
## Obligations

**Deployer's Role:** Operates the AI system and ensures it is used correctly.

**Third-Party Service Provider's Role:** Monitors the system's performance, provides regular reports, and alerts the deployer to potential issues.

## Example

A retail company uses an AI system for inventory management. A third-party service provider monitors the system's performance, providing regular updates and alerting the company to any issues. The company ensures the system operates correctly and informs staff about the AI system.



## Scenario

A deployer, third-party monitoring service, and an authorized representative collaborate. The deployer operates the AI system, the third-party monitors its performance, and the authorized representative ensures that the system's operation remains in compliance with regulatory standards.

## Obligations

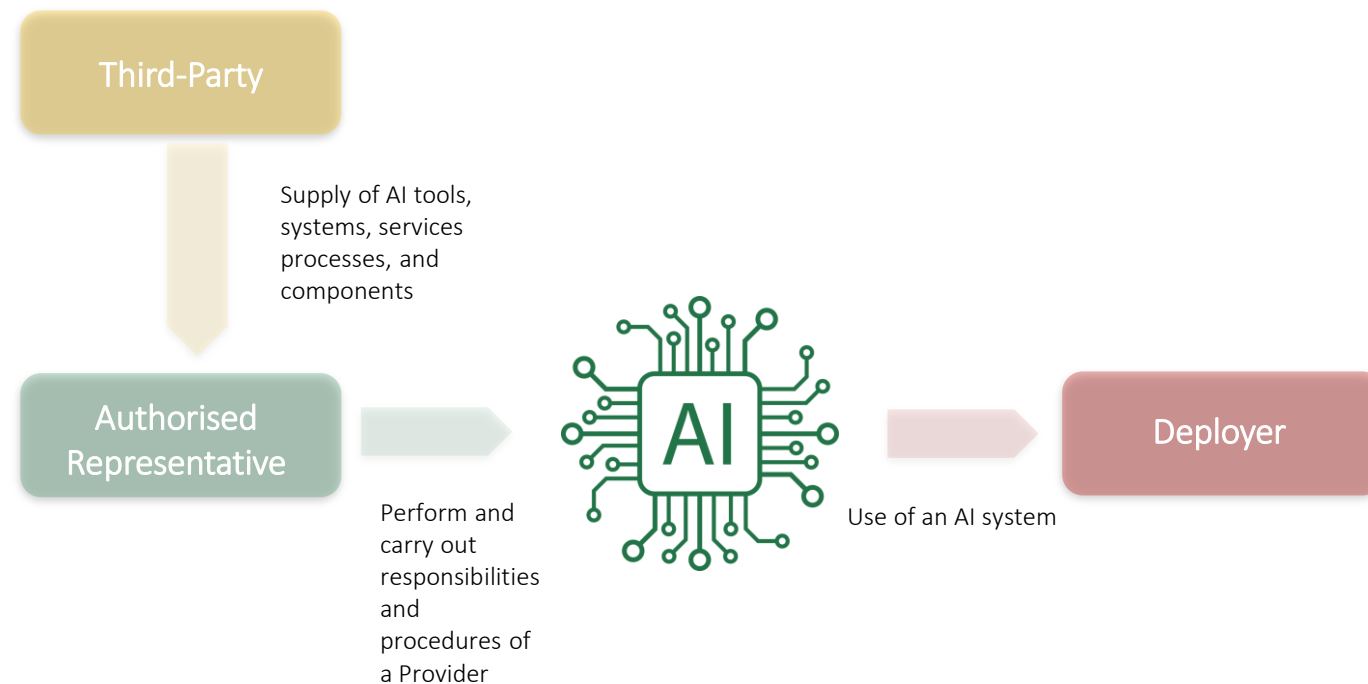
**Deployer's Role:** Operates the AI system and ensures it is used correctly.

**Third-Party Monitoring Service's Role:** Monitors the system's performance, provides regular reports, and alerts the deployer to potential issues.

**Authorized Representative's Role:** Ensures the system's operation remains in compliance with regulatory standards.

## Example

A healthcare provider uses an AI system for patient diagnostics. A third-party service monitors the system's performance, and an authorized representative ensures compliance with regulatory standards. The healthcare provider ensures the system operates correctly, assigns oversight, monitors performance, and informs patients about the AI system.



## — Leveraging cutting-edge insights

- **CEPS**, (2022), “Reconciling the AI Value Chain with the EU’s Artificial Intelligence Act”, accessible at <https://openfuture.eu/wp-content/uploads/2024/03/220930CEPS-In-depth-analysis-AI-act-value-chain.pdf> (last accessed 29th August 2024)
- **European Parliament (EP) and of the Council (EC)**, (2024), “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)”, accessible at [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L\\_202401689](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689) (last accessed 29th August 2024)

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