

Artificial Intelligence Act: Title V - Support of Innovation

European Commission, CNECT A2
October 2021

Overview of Title V Measures in Support of Innovation

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Regulatory
sandboxes

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Other measures to
support small-scale
providers and users

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Links with the actions
under the Coordinated
plan on AI

Objectives:

- Foster innovation
- Support SMEs
- Create an ecosystem of excellence in AI



Regulatory sandboxes (Artt. 53 and 54)

Preliminary considerations

- ▶ Conducive to our twin objectives to achieve both **AI Excellence & Trust**
- ▶ **Council Conclusions** from 2020 on regulatory sandboxes explicitly refer to AI as novel technologies that require flexibility and novel forms of supervision facilitating innovation
- ▶ Sandboxes received **strong support by stakeholders** (during public consultation)
- ▶ Inspired by the **success of existing regulatory sandboxes** (e.g. finance, data protection, energy)

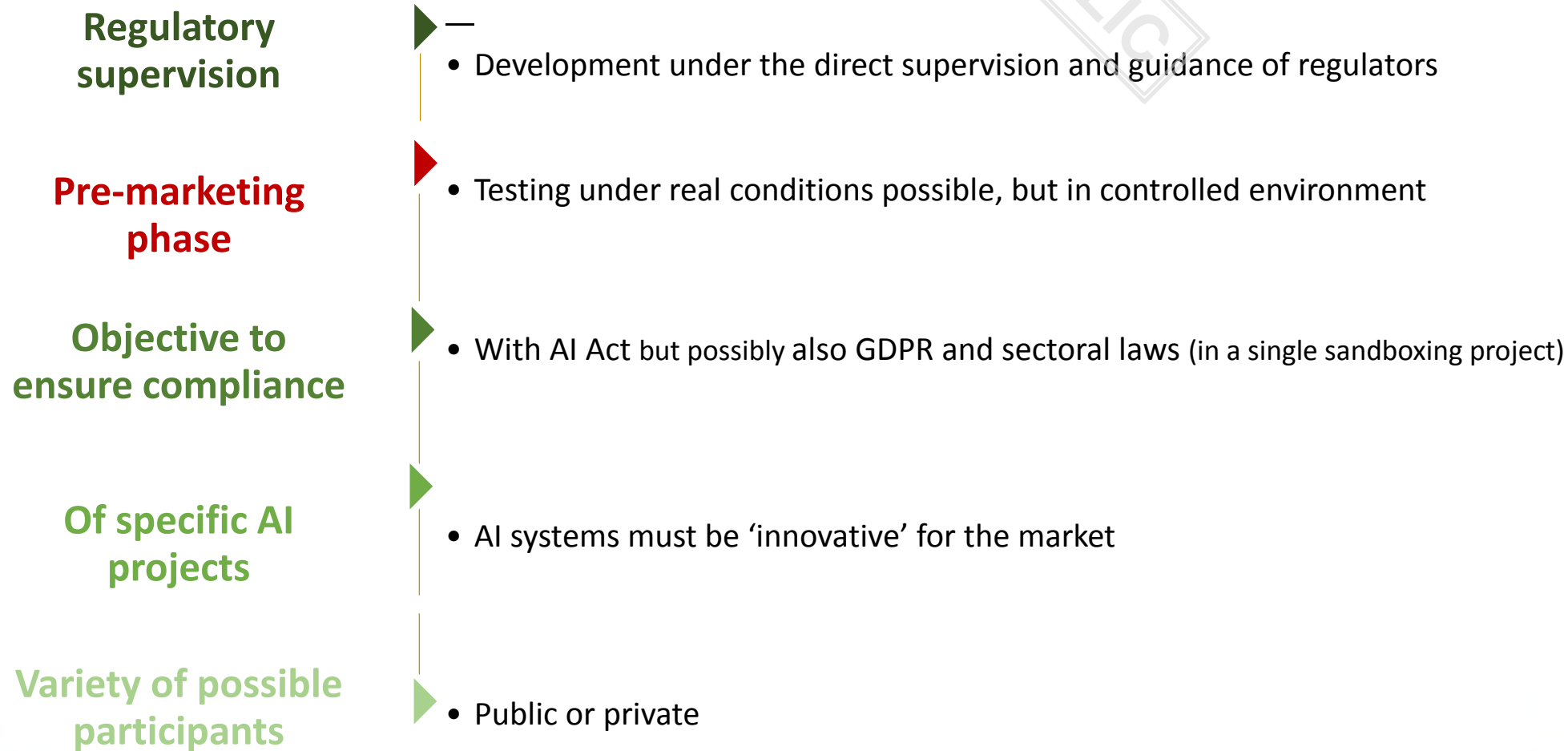
Objectives – recital 72

- ▶ To **foster AI innovation** by establishing a controlled and **safe experimentation** and testing environment in the development and pre-marketing phase
- ▶ To **enhance legal certainty for innovators & the competent authorities' oversight and understanding** of the opportunities, emerging risks and the impacts of AI use
- ▶ To **accelerate access to markets**, including by removing barriers for small and medium enterprises (SMEs) and start-ups

AI Regulatory sandboxes – Article 53 (1)

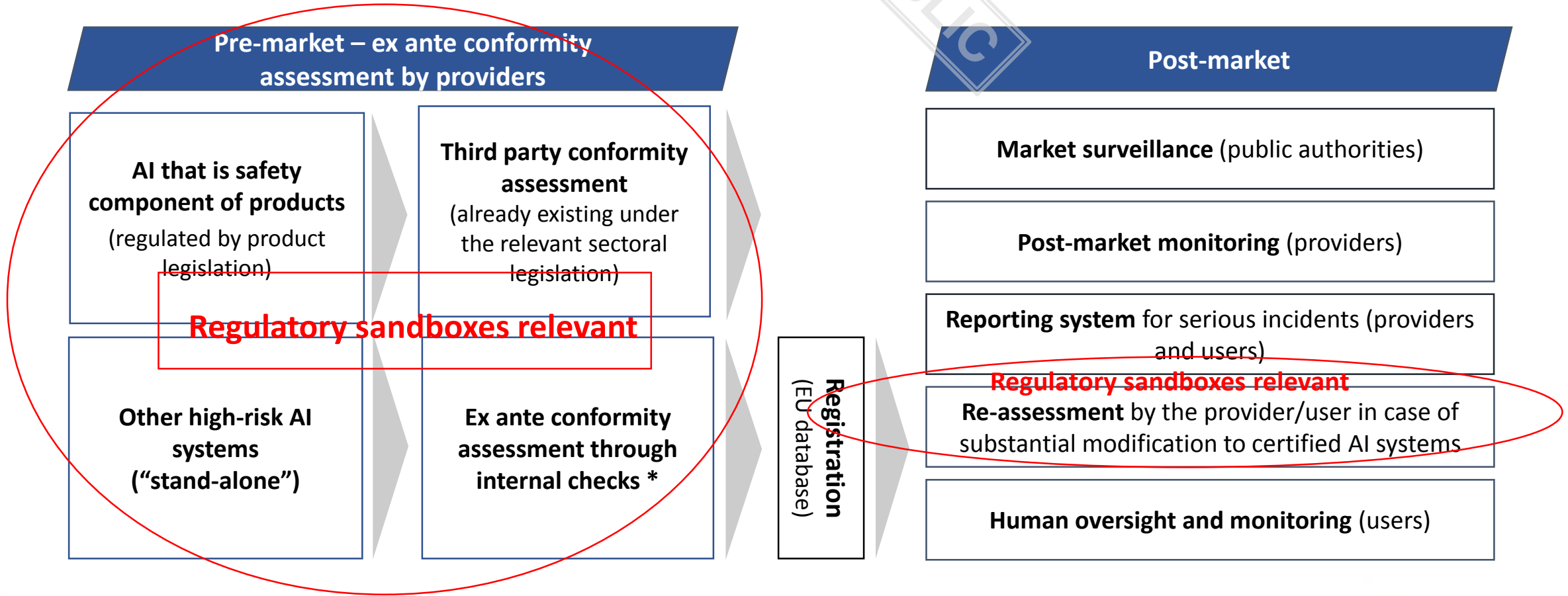
“*AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan.*
This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.”

Key features of AI Regulatory sandboxes



AlA compliance and enforcement system

HIGH RISK



* Exception remote biometric identification - third party

Governance framework – Article 53

National level

- ▶ Established by national **competent authorities**
- ▶ **Association of other relevant regulators** (i.e. data protection, authorities providing or supporting access to data, sectoral supervisory authorities)
- ▶ **Synergies with other initiatives** (data spaces, testing and experimentation facilities funded under DEP)

European level

- ▶ Possibilities for **cross-border European** and **EDPS sandbox**
- ▶ **Coordination and cooperation at EU level** under the EU AI Board
- ▶ **Competent authorities should submit annual reports** to the AI Board and the Commission (incl. good practices, lessons learnt and recommendations)
 - ⚠ Experiences from the sandboxes must be communicated and reproducible to benefit all companies/providers Knowledge-sharing among MS
- ▶ **Single access point to sandbox** applications and information for whole EU (website AI Board/AI on-demand platform)

Operation of the sandbox – Article 53

- ▶ **No derogation from the AI requirements/conformity assessment**

- ▶ But clarity and margin of discretion how regulators apply them to specific AI use cases/projects

- ▶ **Uniform conditions for the operation:** EC implementing acts

- ▶ Eligibility criteria

- ▶ Procedure for application, selection, participation and exiting from the sandbox
 - ▶ Rights and obligations of the participants

- a) **Prevent market fragmentation**
 - b) **Level playing field**
 - c) **Flexibility** (can be easily adapted)

- ▶ Key elements defined in the AI Act:

- ▶ **Regulatory guidance for specific needs:** participation to be based on a specific plan
 - ▶ **Risk management:** any significant risks to health and safety and fundamental rights identified during the testing should result in immediate mitigation and, failing that, in the suspension of the testing process
 - ▶ **Supervisory and corrective powers of authorities unaffected** but conduct of participants to be taken into account for the purpose of possible sanction (recital 72)
 - ▶ Participants **remain liable** under applicable liability legislation

Special regime for re-use of personal data in the AI regulatory sandbox – art. 54

Art. 6(4)
GDPR
compliant

- ▶ Provides **a legal basis for the re-use**/further processing of personal data for developing certain AI systems in the public interest in one or more of the following areas:
 - I. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;
 - II. Public safety and public health, including disease prevention, control and treatment;
 - III. A high level of protection and improvement of the quality of the environment;
- ▶ Subject to **additional safeguards** including:
 - ▶ Data processed should be necessary for fulfilling one or more of the AI requirements (which cannot be effectively achieved by synthetic and non-personal data)
 - ▶ Effective monitoring mechanisms to identify high risks to fundamental rights
 - ▶ Processing should not lead to measures or decisions affecting the data subjects;
 - ▶ Specific storage, access, security and documentation requirements



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**Other support
(Art. 55,
recitals 45, 73-75)**

Measures for 'small-scale' providers and users- Article 55

*means 'a provider/user that is a **micro or small enterprise** within the meaning of Commission Recommendation 2003/361/EC' (Art.3(3) AIA)*

Member States shall undertake the following actions:

- ▶ priority access to the AI regulatory sandboxes
- ▶ organise specific awareness raising activities about the application of this Regulation
- ▶ establish a dedicated channel for communication to provide guidance and respond to queries

Measures to reduce costs

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“Article 55(2) - The specific interests and needs of the small-scale providers shall be taken into account when **setting the fees for conformity assessment**, reducing those fees proportionately to their size and market size.’

“Recital 73 – Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that **one of the languages determined and accepted by them for relevant providers’ documentation and for communication with operators is one which is broadly understood** by the largest possible number of cross-border users.”

Measures to facilitate implementation

Link with the
Coordinated plan
on AI

*“Recital 74 - In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, **the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities** established by the Commission and the Member States at national or EU level should possibly contribute to the implementation of this Regulation. **Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.**”*

*“Recital 75 - It is appropriate that **the Commission facilitates, to the extent possible, access to Testing and Experimentation Facilities to bodies, groups or laboratories** established or accredited pursuant to any relevant Union harmonisation legislation and which fulfil tasks in the context of conformity assessment of products or devices covered by that Union harmonisation legislation. This is notably the case for expert panels, expert laboratories and reference laboratories in the field of medical devices pursuant to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.”*

Measures to facilitate access to data

Link with the
Coordinated plan
on AI

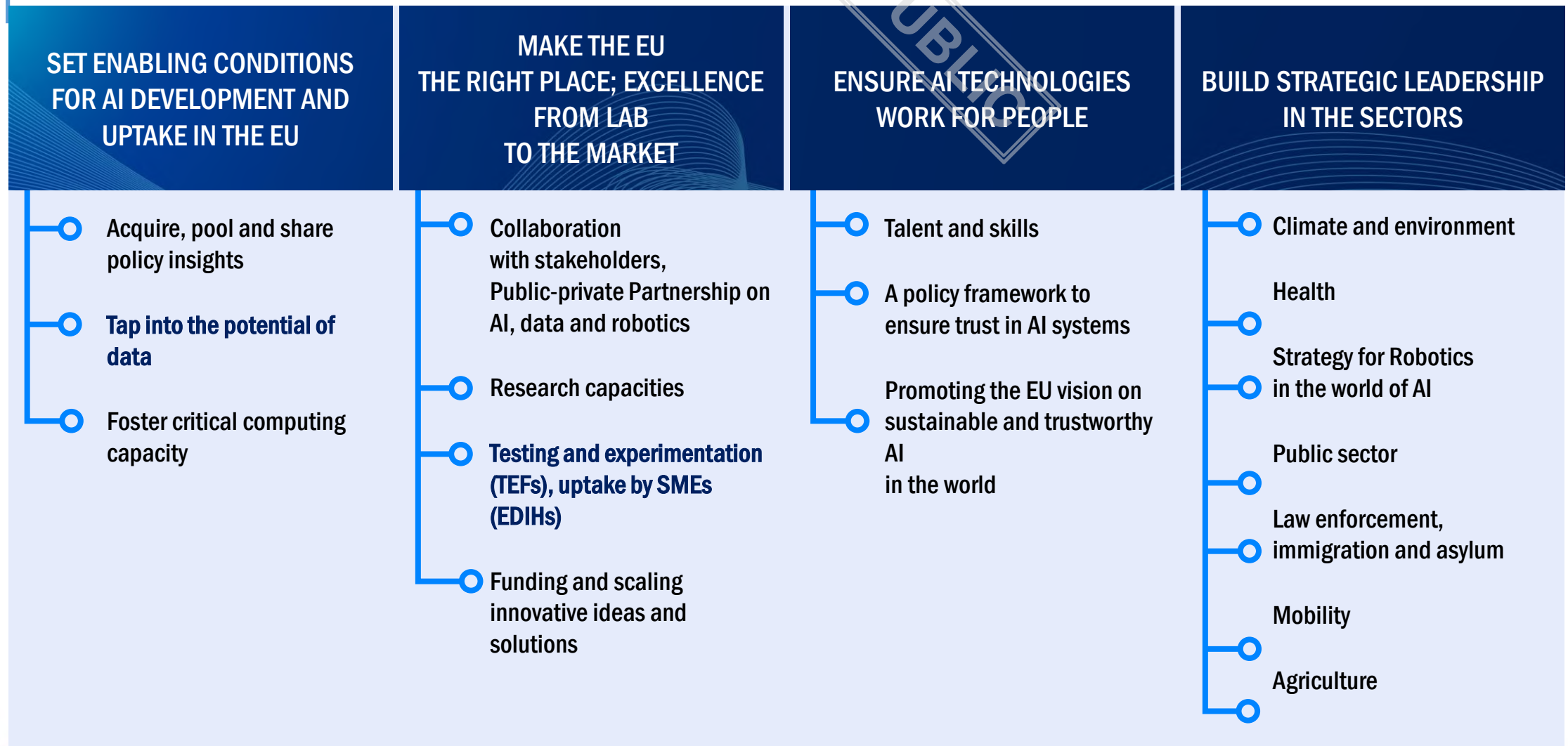
“ Recital 45 - *For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. **European common data spaces** established by the Commission and **the facilitation of data sharing between businesses and with government** in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. **Relevant competent authorities, including sectoral ones, providing or supporting the access to data** may also support the provision of high-quality data for the training, validation and testing of AI systems.* ”



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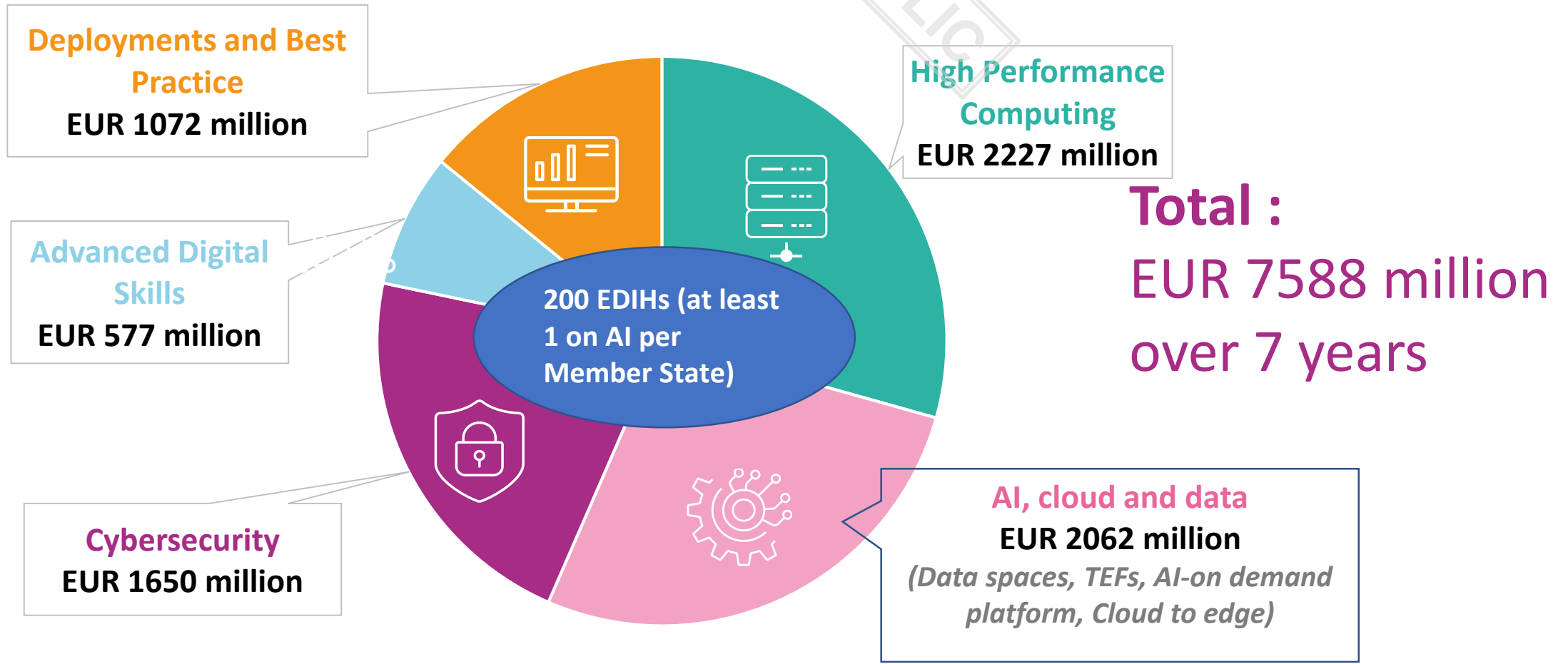
Background: Links with the actions under the Coordinated plan on AI

Support measures under the 2021 Coordinated Plan on AI (review from 2018)

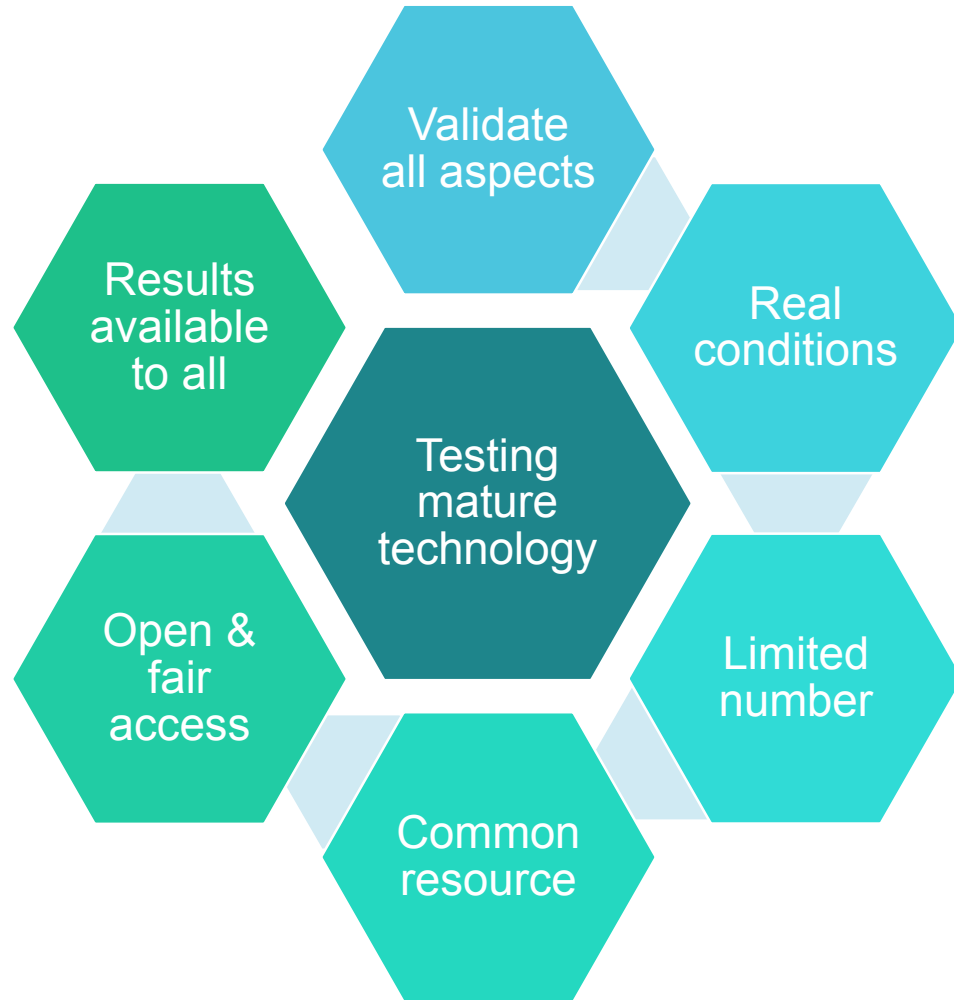


Investments: Horizon Europe, Digital Europe, Recovery and Resilience Facility

Digital Europe Programme: Budget



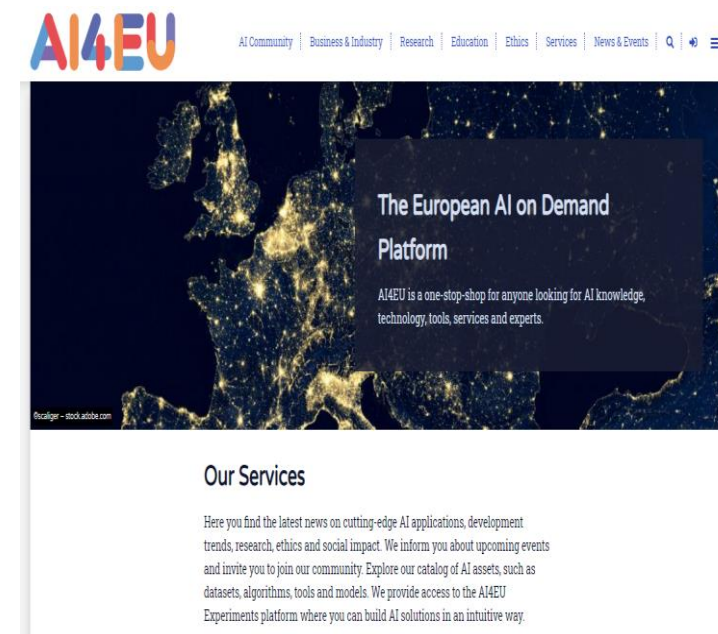
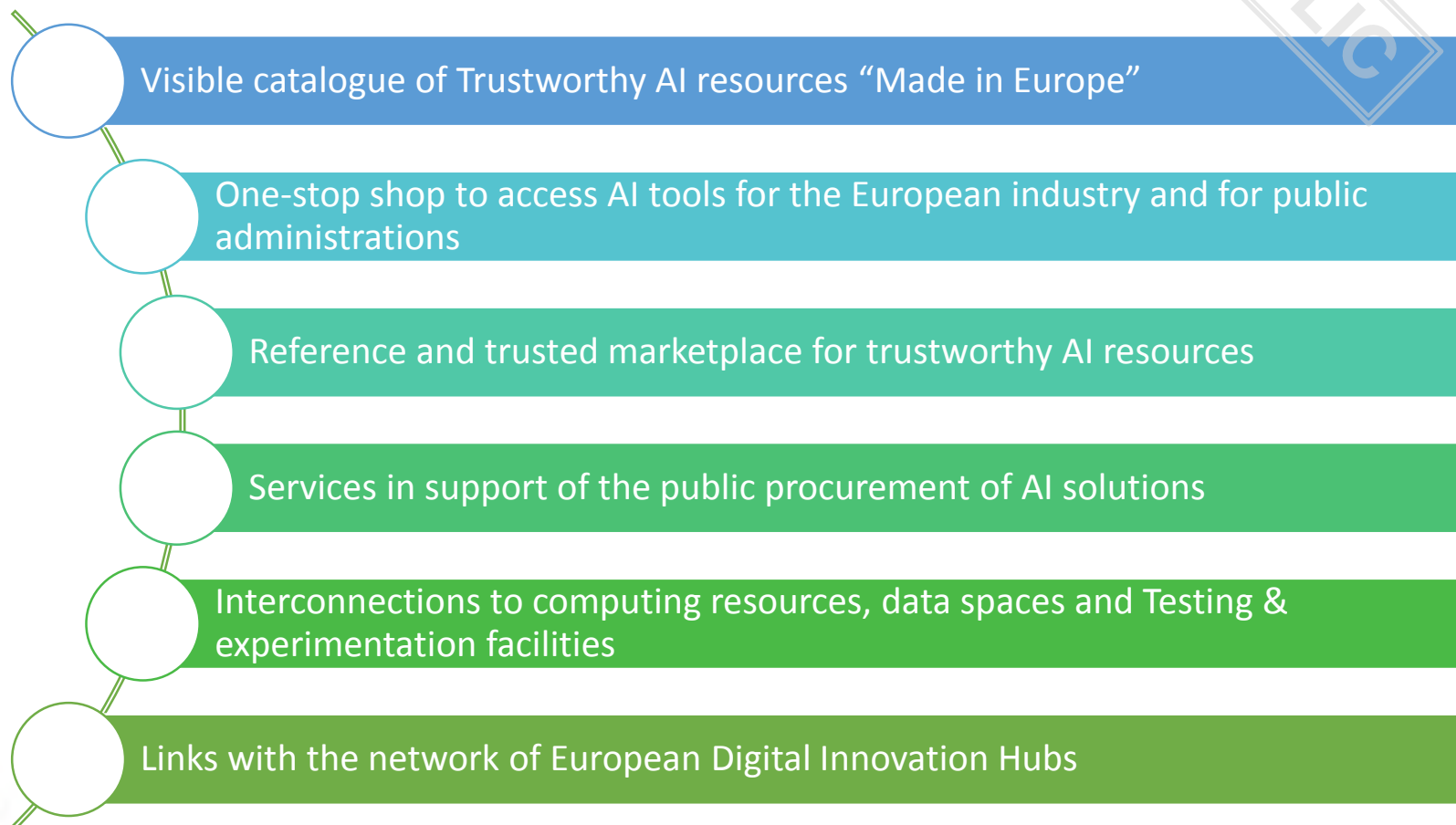
Testing and Experimentation Facilities (TEFs)



- World class reference sites for experimentation and testing AI in real settings
- Essential sectors: Agri-food, Healthcare, Manufacturing and Smart Cities & Communities
- Equipped with infrastructure & latest AI + Access to cloud/Data/HPC

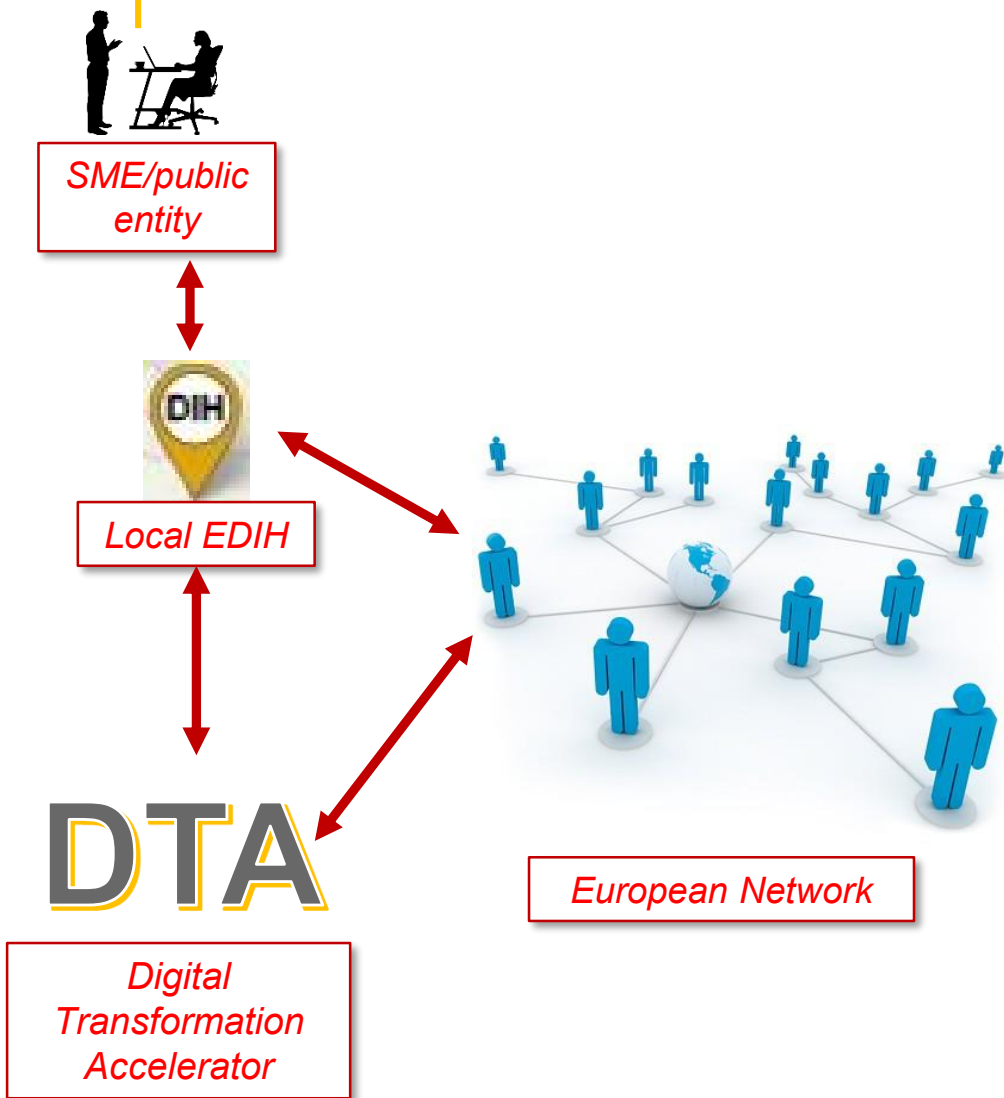
The AI on demand platform

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<https://www.ai4europe.eu/>

Network of 200 European Digital Innovation Hubs (EDIHs)



- Offer support for digital transformation of SMEs and public authorities which is adapted to local needs
- At least, **1 EDIH specialized in AI** in each Member State – advice and support test and uptake of AI solutions
- Build regional ecosystems of users and suppliers, strengthening local innovation environment
- Connect to the whole of Europe through the network:
 - Share best practices with other hubs
 - Connect local SMEs to SMEs outside the region, building new value chains in Europe
 - Disseminate digital capacities of Digital Europe Programme to local community



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Thank you



Council of the European Union
General Secretariat

Brussels, 12 October 2021

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WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Artificial Intelligence Act - PowerPoint Presentation : TITLE V - Support of Innovation

Delegations will find in annex the PowerPoint Presentation on Artificial Intelligence Act (Title V - Support of Innovation) made by the Commission at the Telecommunications and Information Society Working Party on 12 October 2021.