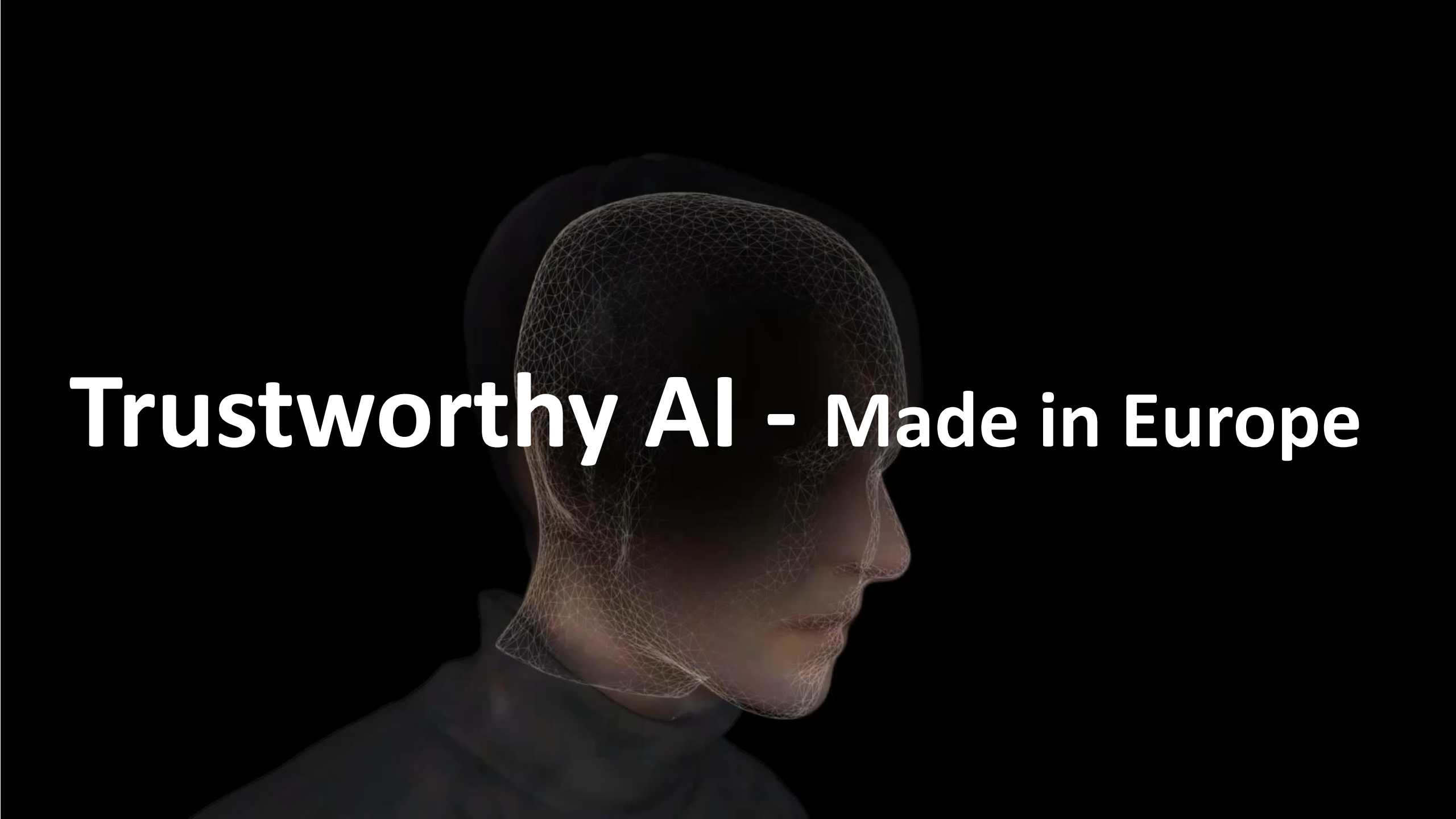
European Testing and Experimentation Facility for Health AI and Robotics

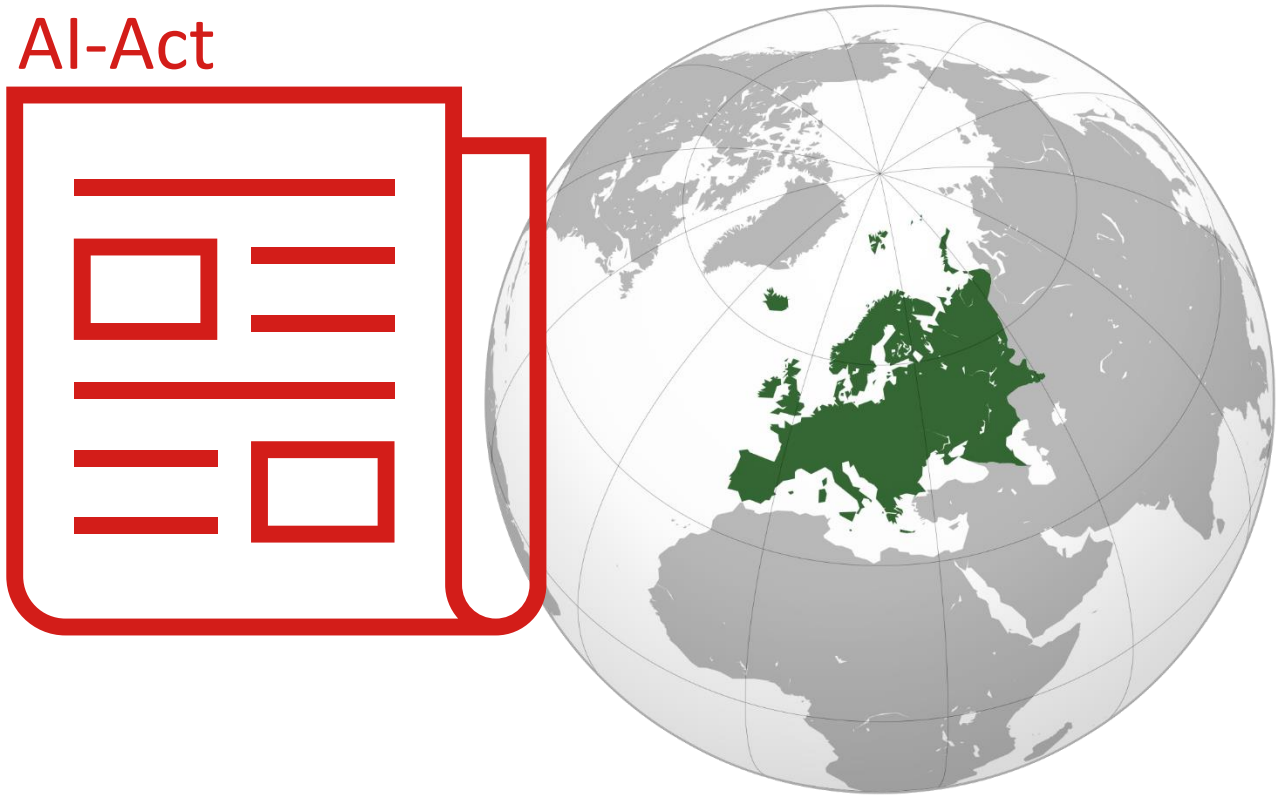
Prof. Dr. Petra Ritter (Coordinator TEF-Health)

Charité Universitätsmedizin Berlin, Berlin Institute of Health

Co-funded by the European Union DIGITAL Europe - 101100700


Trustworthy AI - Made in Europe

EU AI Act - the world's first regional regulation to enforce trustworthy AI



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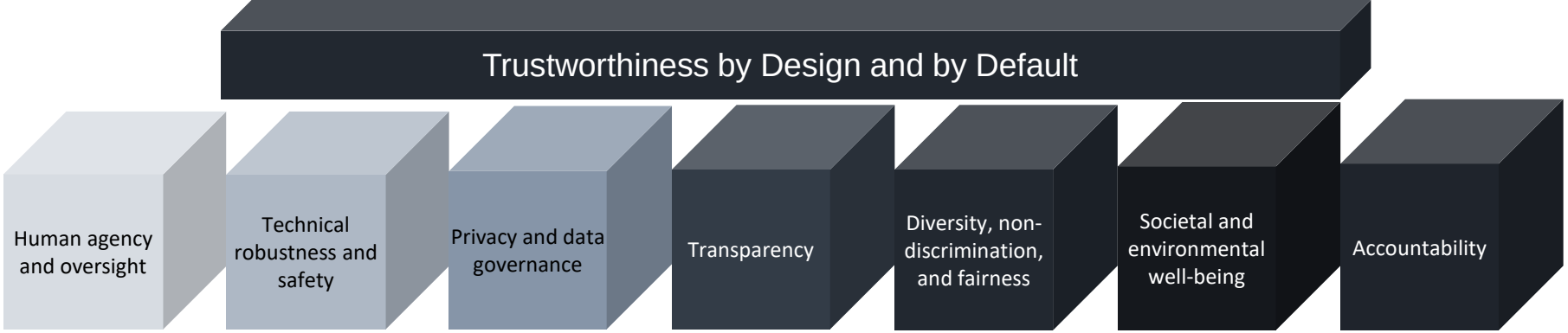
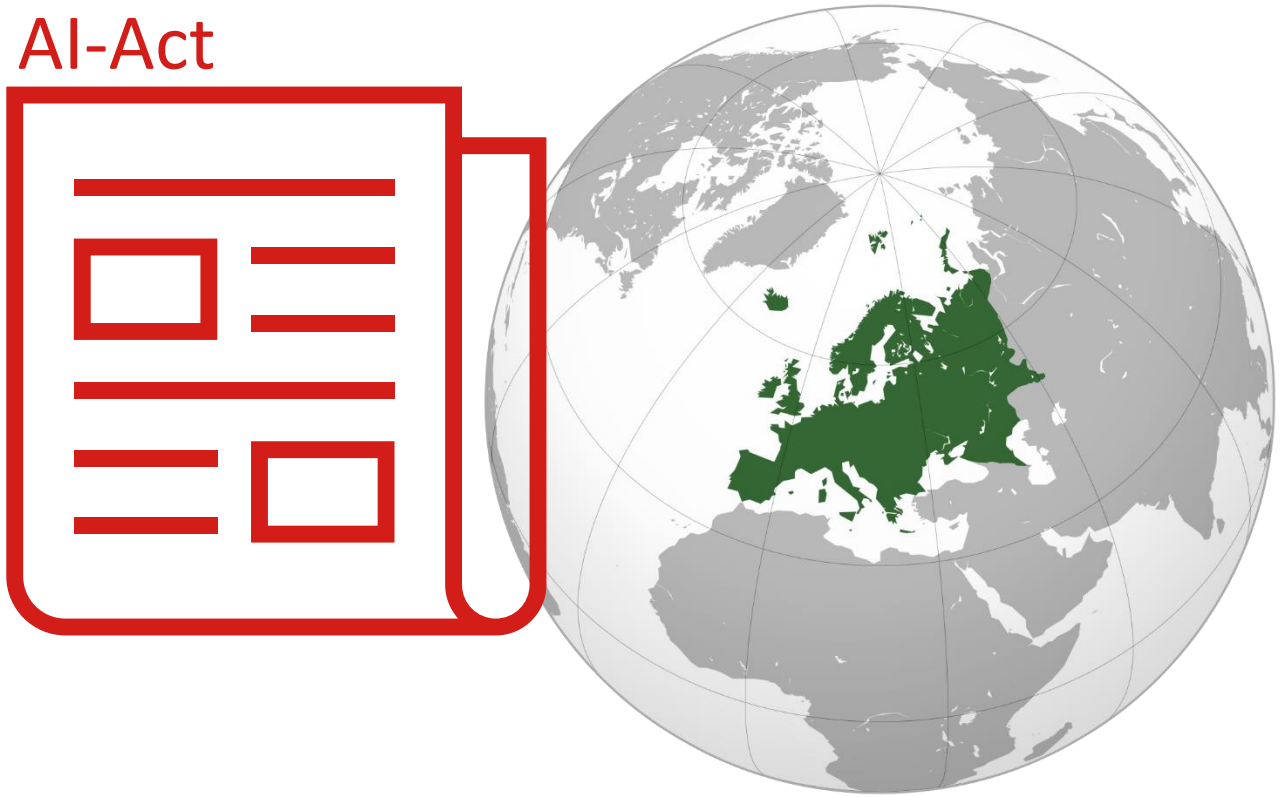
AI-Act


Trustworthiness by Design and by Default
Human agency and oversight
Technical robustness and safety
Privacy and data governance
Transparency
Diversity, non-discrimination, and fairness
Societal and environmental well-being
Accountability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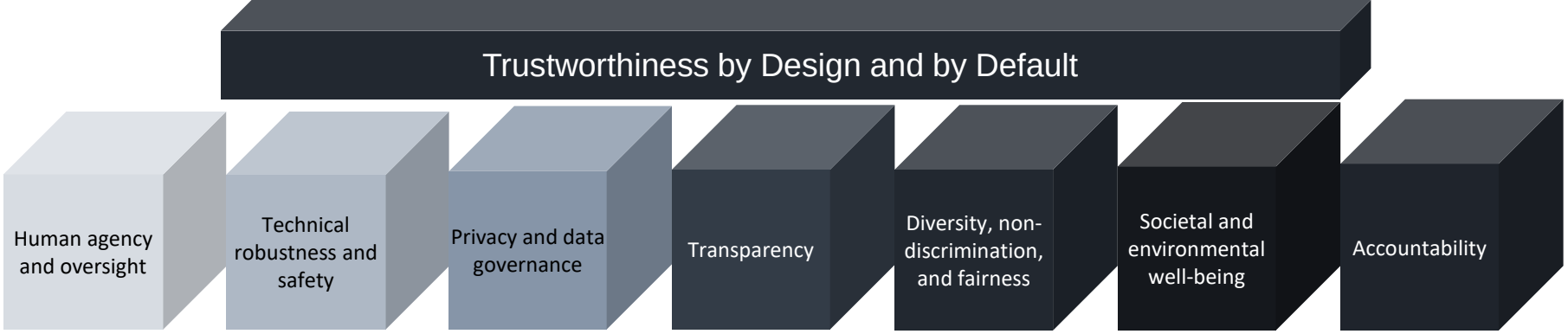

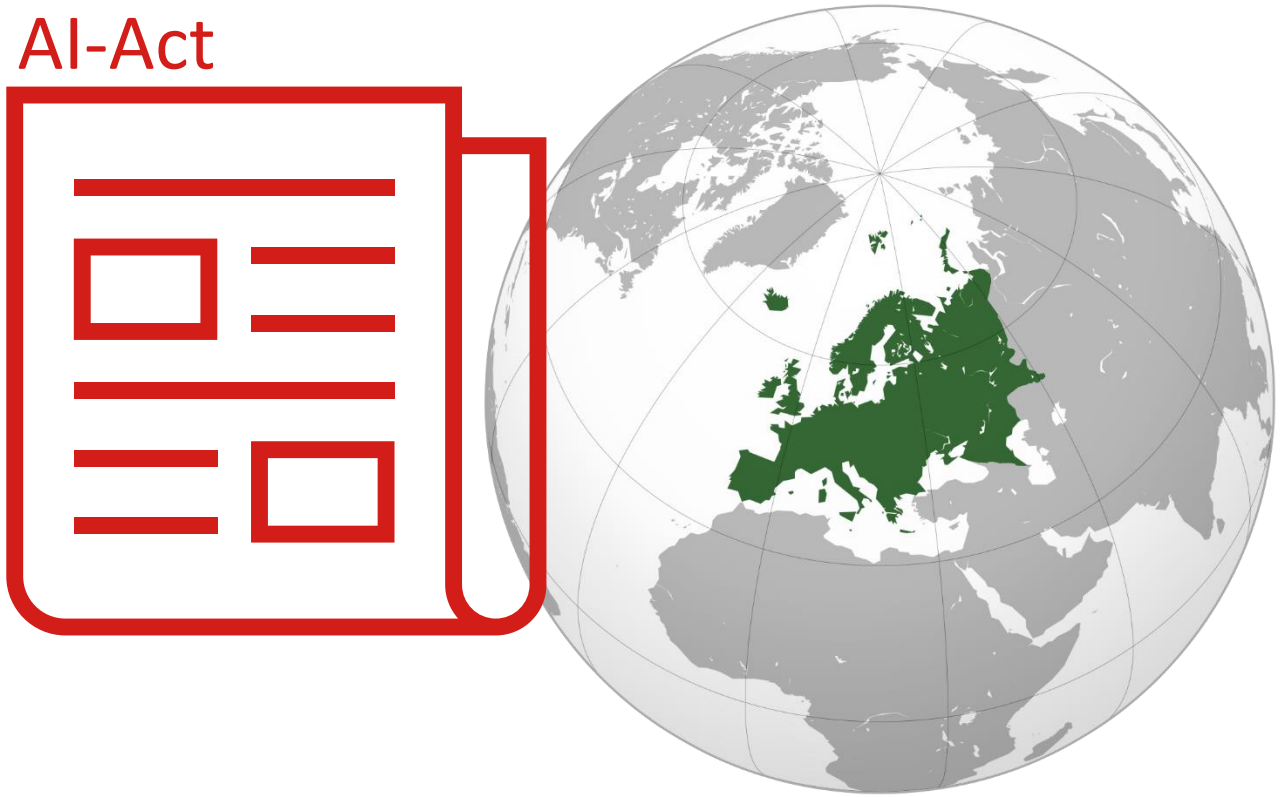

Testing and Experimentation Facilities (TEFs)

As implementation instrument

§

TEFs provide „technical and scientific support for providers and notified bodies“

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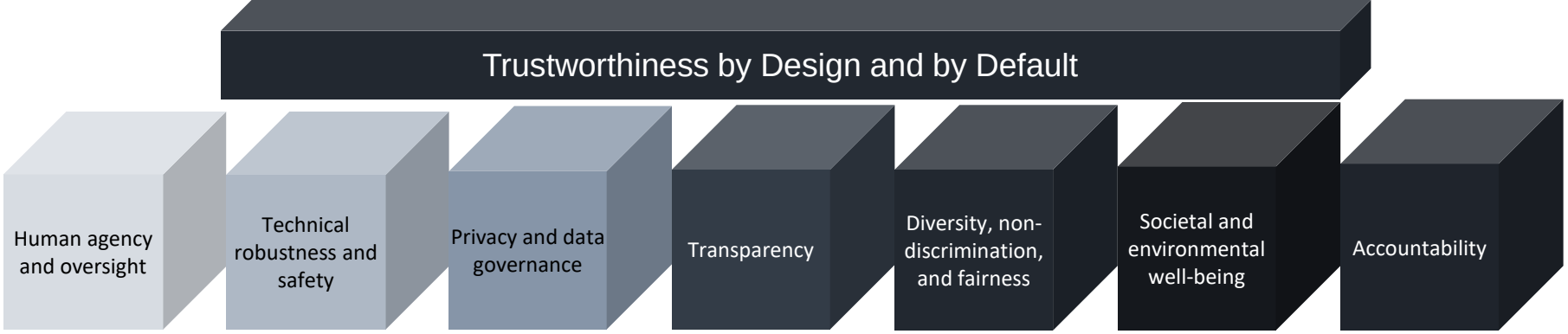
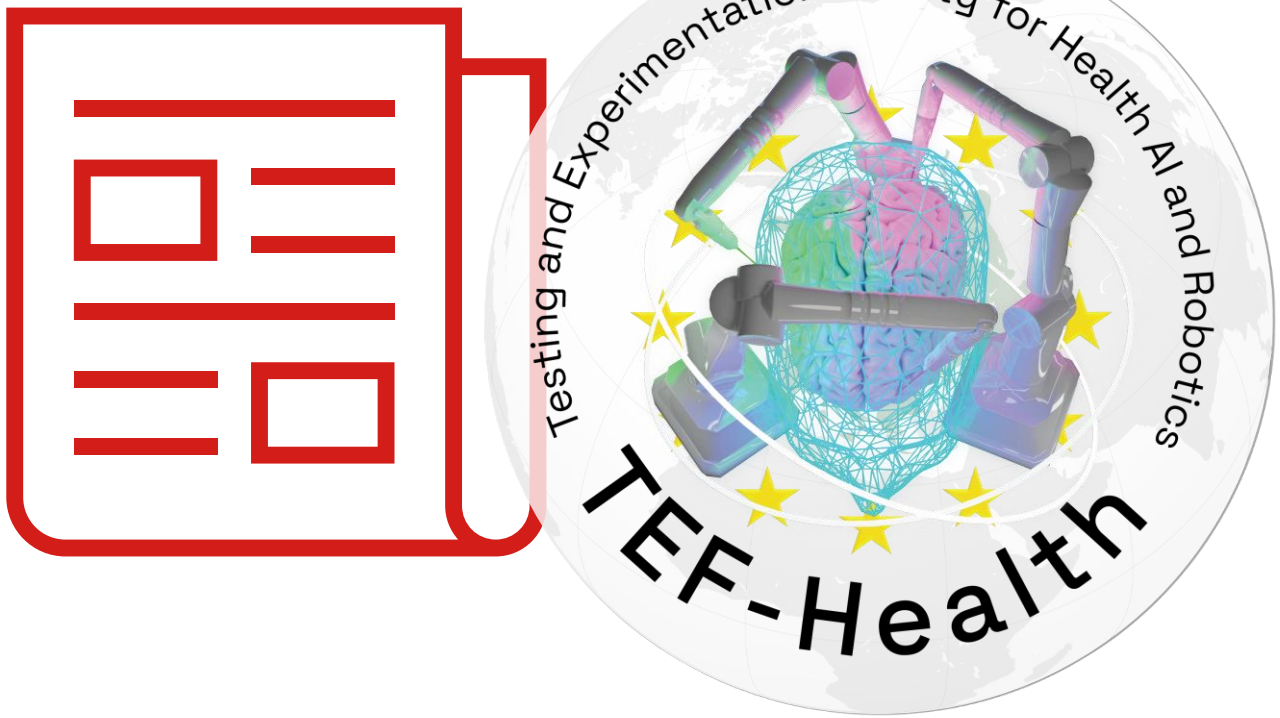
AI-Act



AI-Act



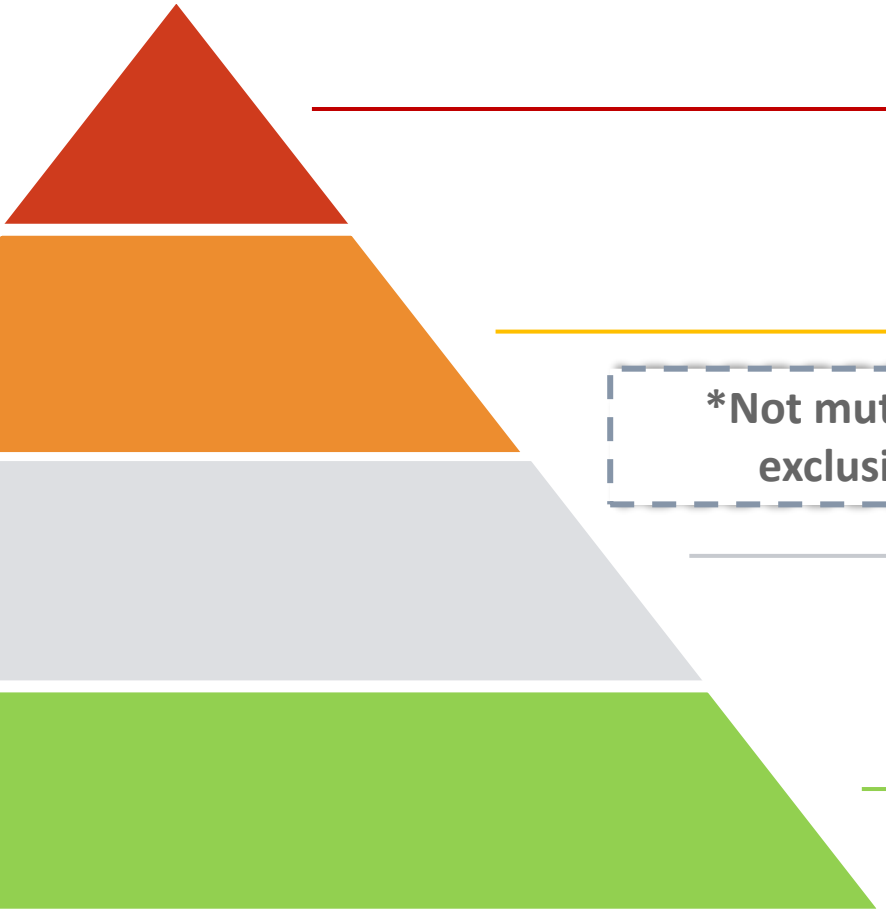
Testing and Experimentation Facilities (TEFs)

As implementation instrument

§

TEFs provide „technical and scientific support for providers and notified bodies“

Medical devices with AI systems are classified “high risk” and require conformity assessment



*Not mutually exclusive

Unacceptable risk
e.g. social scoring, untargeted scraping
— **Prohibited**

High risk
e.g. recruitment, medical devices
— **Permitted** subject to compliance with AI requirements and ex-ante conformity assessment

‘Transparency’ risk
‘Impersonation’ (chatbots), deep fakes
— **Permitted** but subject to information/transparency obligations

Minimal or no risk
— **Permitted** with no restrictions, voluntary codes of conduct possible

Source: EC Unit A.2 Info Session presentation March 18, 2024 Webinar

Flywheel from lab to market

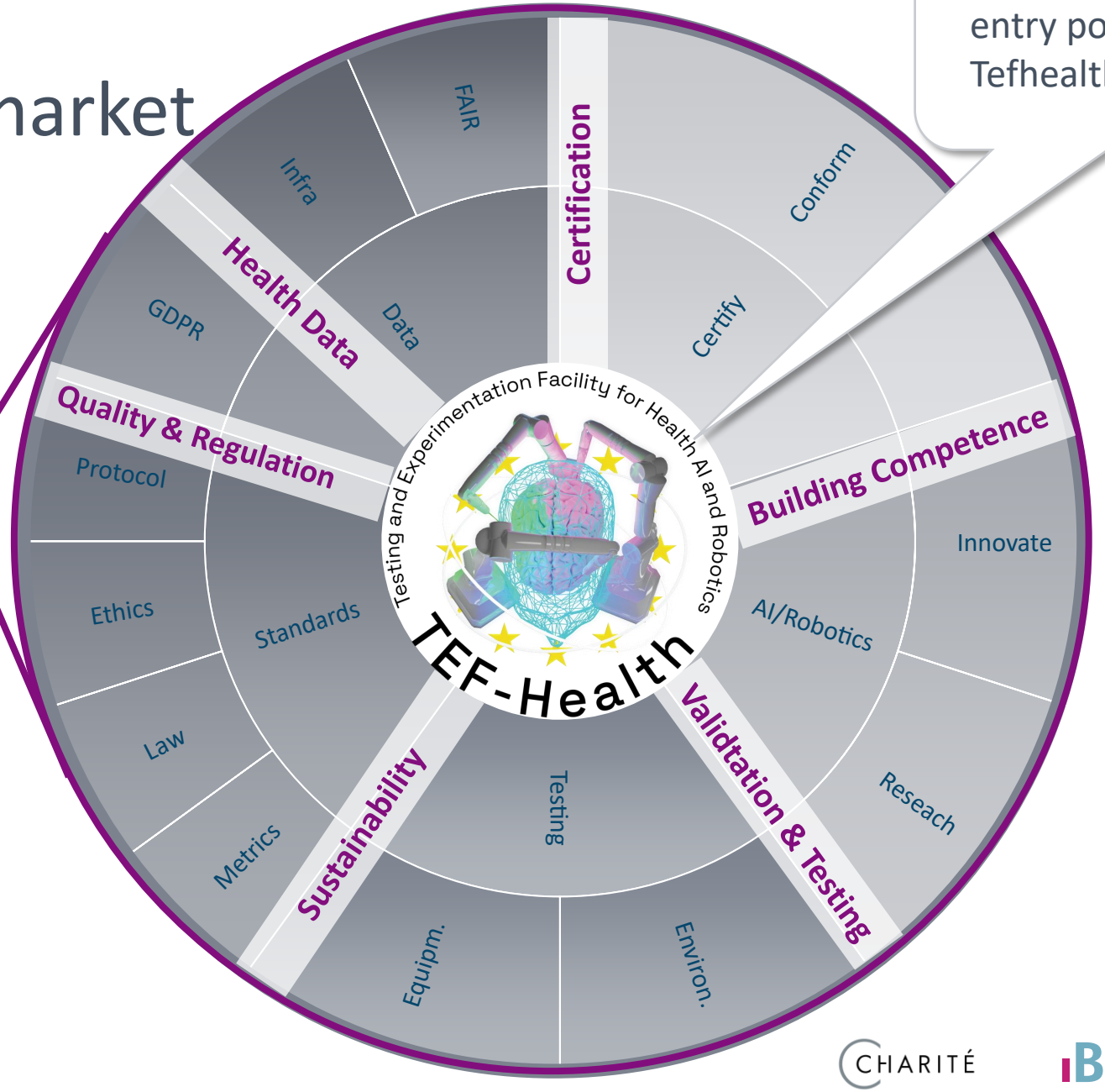
- Idea
- Research
- Data, Knowledge

Lab

- Data driven innovation and validation
- Testing
- Certification

Bed

- Marketable product



Single EU-wide entry point through Tefhealth.eu

Service Categories:

- Data
- Standards
- Testing
- AI/Robotics
- Certify

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Testing and Experimentation Facility – 52 partner organizations under the lead of Charité University Medicine, Berlin, Germany

Testing and Experimentation Facility for Health AI and Robotics

TEF-Health

GERMANY

Berlin	CHARITÉ*, BPWT°, VdTÜV•, KI Park•
Braunschweig	PTB*
Erlangen	FAU*
Heidelberg	EIT H SI GmbH°
München	TUM*, FHG•,EIT HEALTH EV°

BELGIUM

Charleroi	ISPPC°, CETIC•, BIOWIN•
Liège	WSL°
Mol	VITO•
Mons	MULTITEL•
Namur	UNamur•, POLEM•

FRANCE

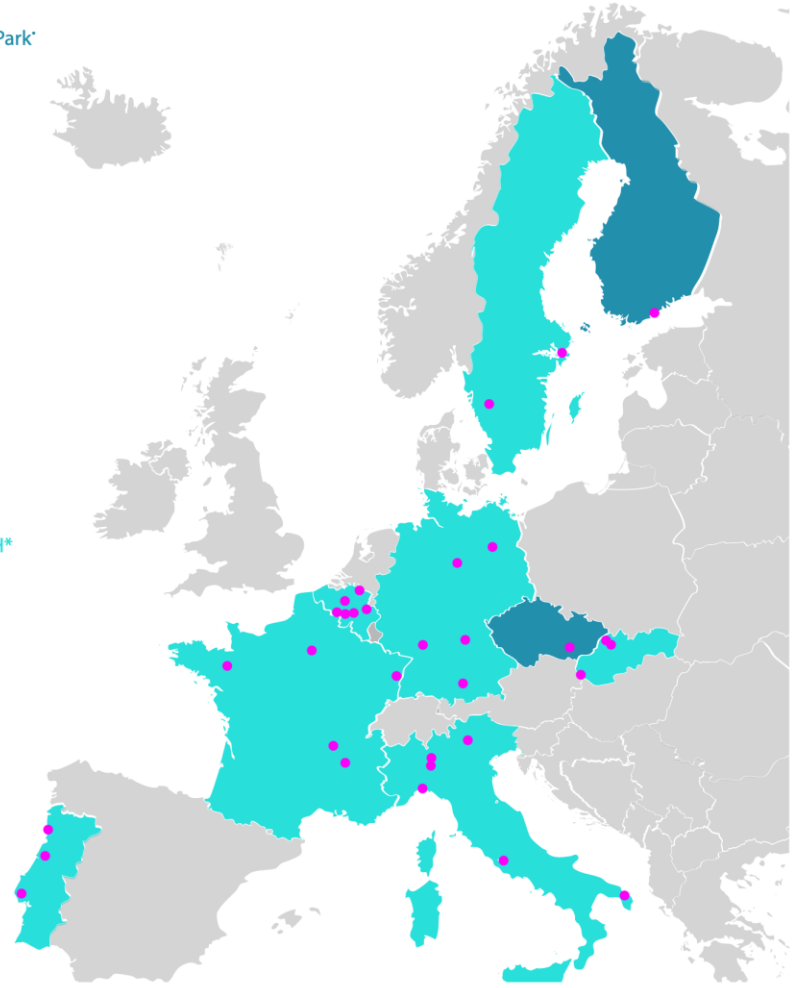
Grenoble	CHUGA*, UGA*
Lyon	HCL*
Paris	LNE,* CEA*, EIT Health Fr•, HDH*
Rennes	CHU RENNES*
Strasbourg	IHUS•

ITALY

Genova	IGG*, IIT•
Lecce	INNOVAAL•
Milano	POLIMI*
Pavia	UNIPV*
Povo	FBK•
Roma	ISS*

PORTUGAL

Coimbra	IPN•, CHUC EPE*
Lisboa	SPMS*,InnoStars •
Porto	CHSJ*, HCP•



SLOVAKIA

Bratislava	UK BA*, STUBA*
Martin	UHM*
Zilina	UNIZA*

SWEDEN

Boras	RISE•
Stockholm	KI*

PAN-UE

Brussels	EBRAINS•

CZECHIA

BRNO	MU*

FINLAND

Helsinki	HELSINGFORS*, HUS*, METROPOLIA•

Node & Node Lead

Associated & Associated Lead

* Public, Non-profit

• Private, Non-profit

° Private, Profit

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Infrastructure for compliance testing

AI Innovators

(Realtime) Compliance

Production factory of test results

Service providers

Authorized certifiers

- Digital infrastructure for information synchronization
- Continuous evaluation of predetermined changes
- One stop shop access to all relevant resources

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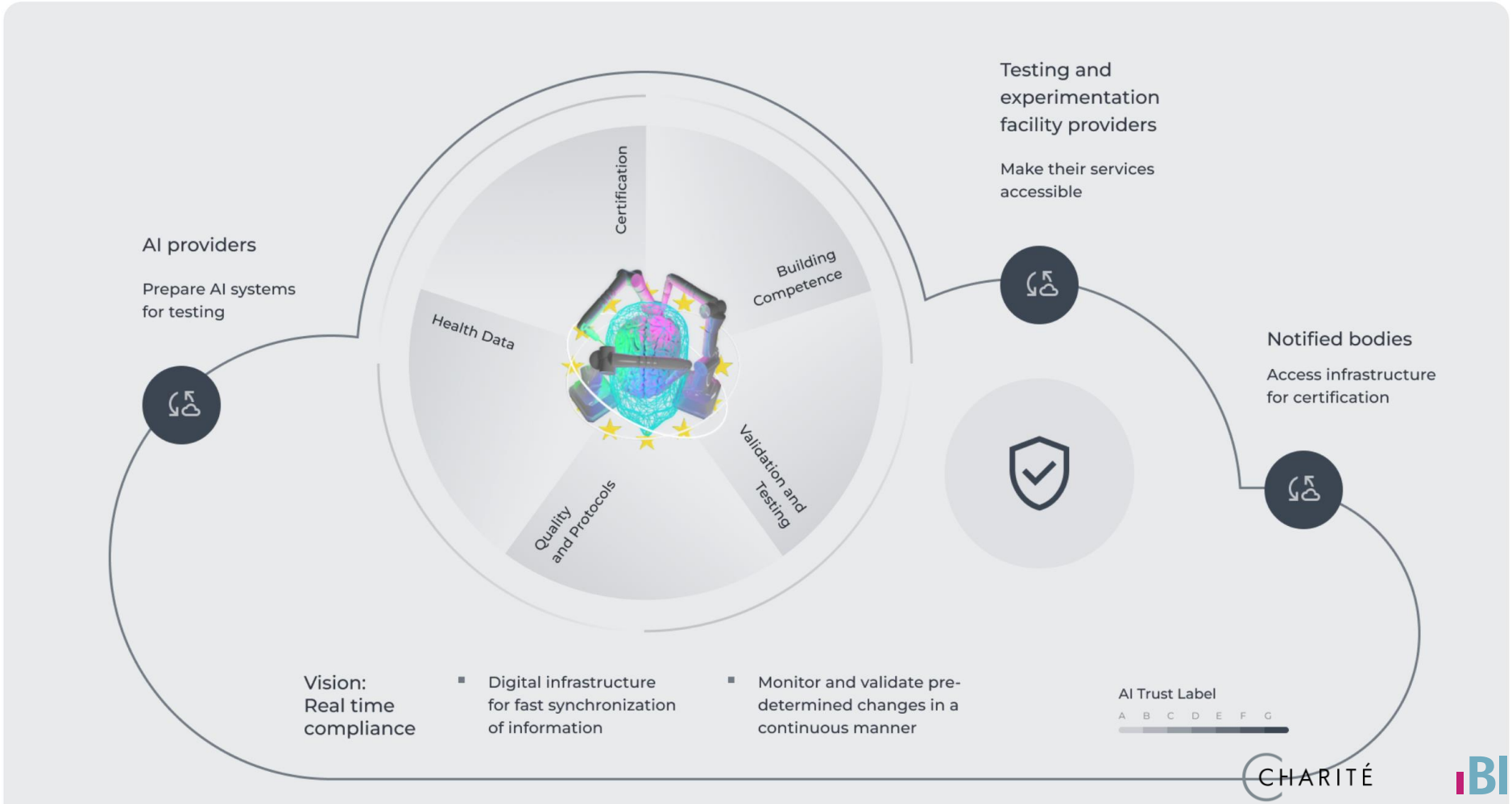
Technical and scientific support for Health AI providers and notified bodies



TEF-Health
Testing and Experimentation Facility for Health AI and Robotics

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CATEGORIES

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Interoperable imaging testing

Provided by : Politecnico Di Milano

Technical Documentation

Privacy enhancing technologies development and testing

Provided by : RISE Research Institutes of Sweden Ab, Boras

Data integration consulting

Provided by : Instituto Pedro Nunes Associacao Para A Inovacao E Desenvolvimento Em Ciencia E Tecnologia Coimbra

Interoperability assessment

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Thank you!

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