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21 MAIO | ISCTE LISBOA

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FCT Fundação para a Ciência e a Tecnologia

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

apifarma
ASSOCIAÇÃO PORTUGUESA DA INDÚSTRIA FARMACÊUTICA

Health Cluster Portugal

PtCRIN
PORTUGUESE CLINICAL RESEARCH INFRASTRUCTURE NETWORK

iscte INSTITUTO UNIVERSITÁRIO DE LISBOA

Aumentar o impacto da inteligência artificial e robótica na inovação biomédica através de uma rede europeia de testes e validação

**António Lindo da Cunha**

Instituto Pedro Nunes

Medtech in Europe

The European MedTech sector has around 27.000 companies, 95% of which are SMEs. These companies need to demonstrate not only **safety** and **performance** over the entire life cycle of a product, but also **tangible benefits for the patients and the healthcare system.**

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Innovation Value Chain Gap in Medtech (TRL approach)
Empirical perception
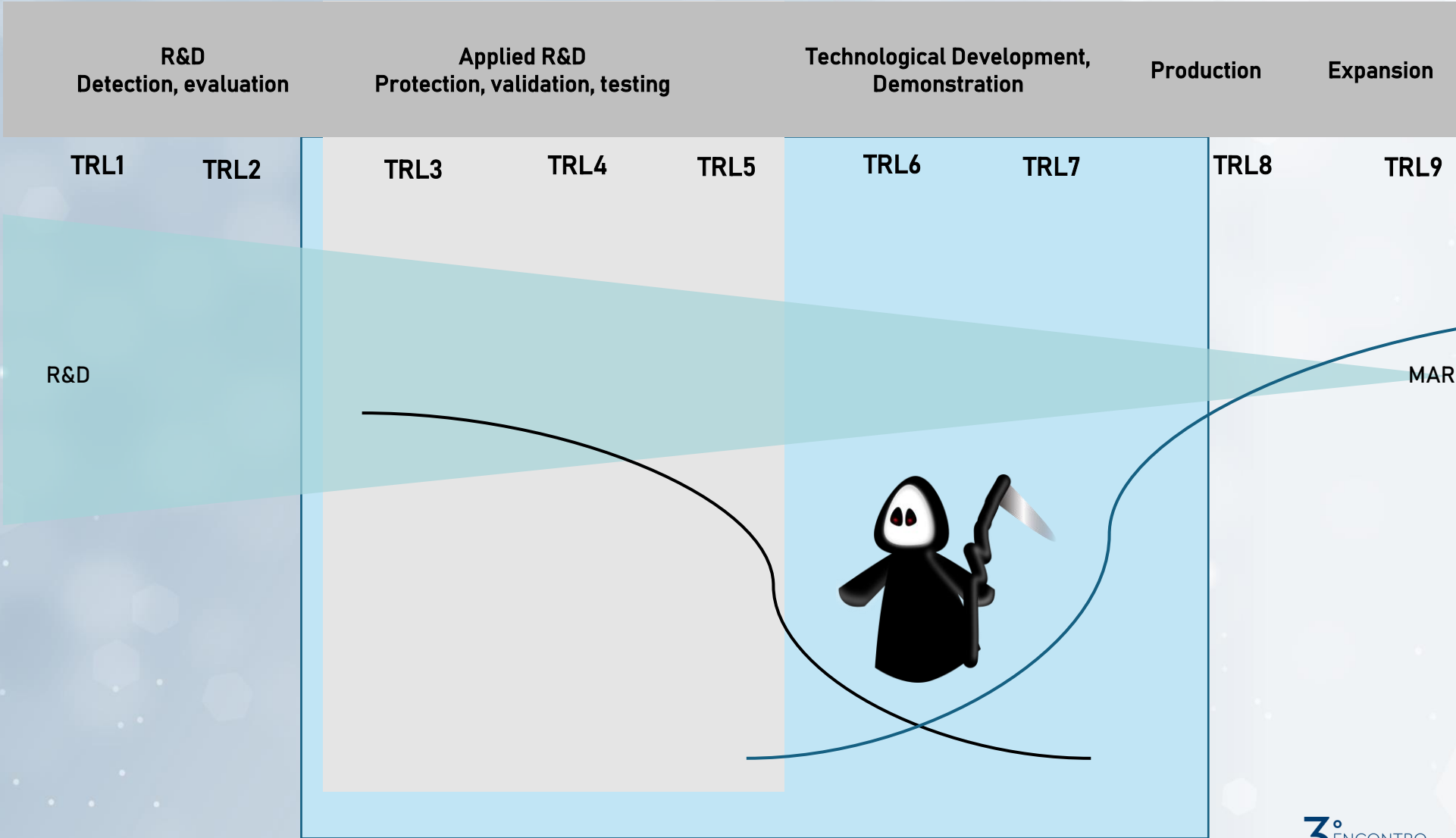
Innovation Value Chain Gap (CIMIT approach)
Empirical perception
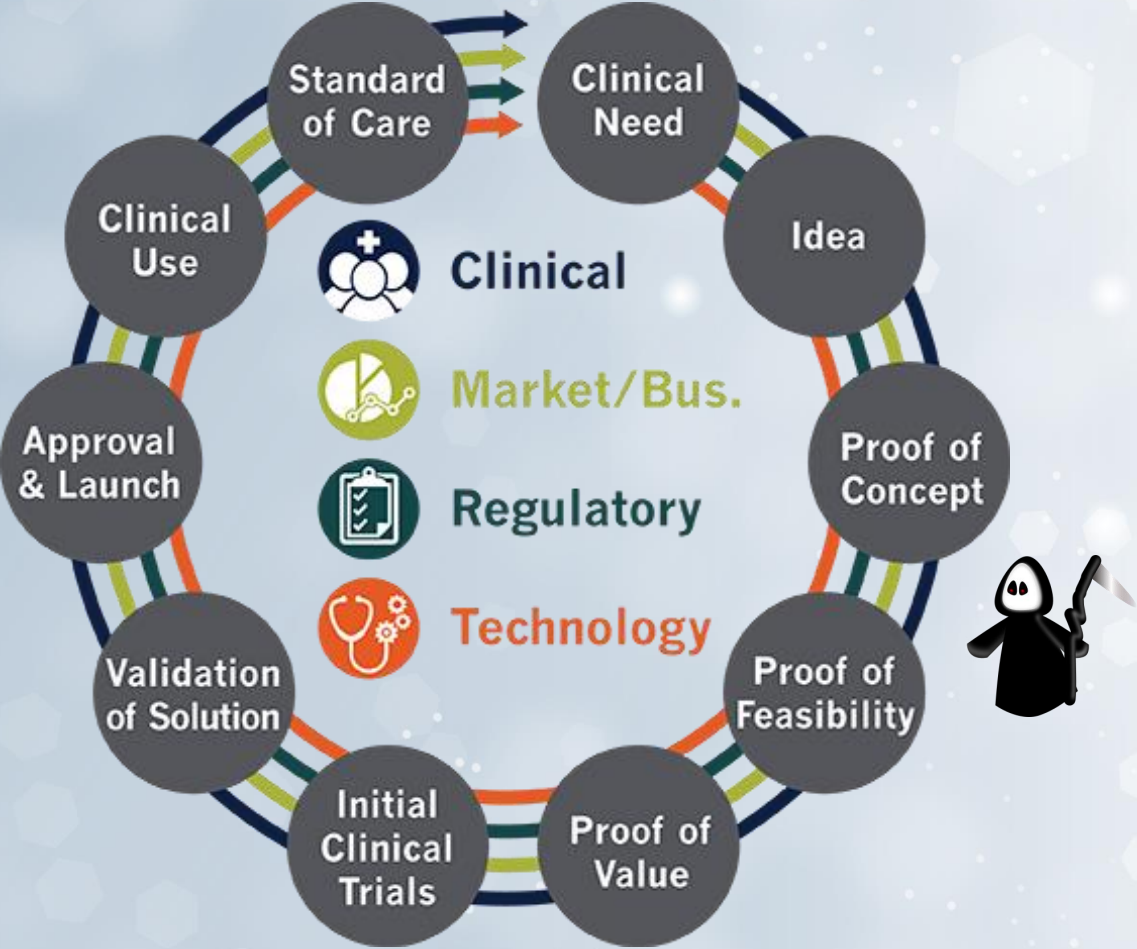
"More than 300,000 health applications exist with more than 200 added daily. "

"However, an evaluation of 280 diabetes mobile applications found only 5 associated with clinically meaningful improvement and none were of high methodological quality."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10799285/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6232741/

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"A 2020 assessment of the regulatory status of paediatric drug calculator apps made available to the EU market, which have an **intended purpose classifying them as medical devices**, found that one only out of 74 apps (1.4%) had the necessary regulatory approval."

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"App stores must ensure through verification checks that apps comply with specific requirements in the regulation EU MDR, and remove noncompliant apps."
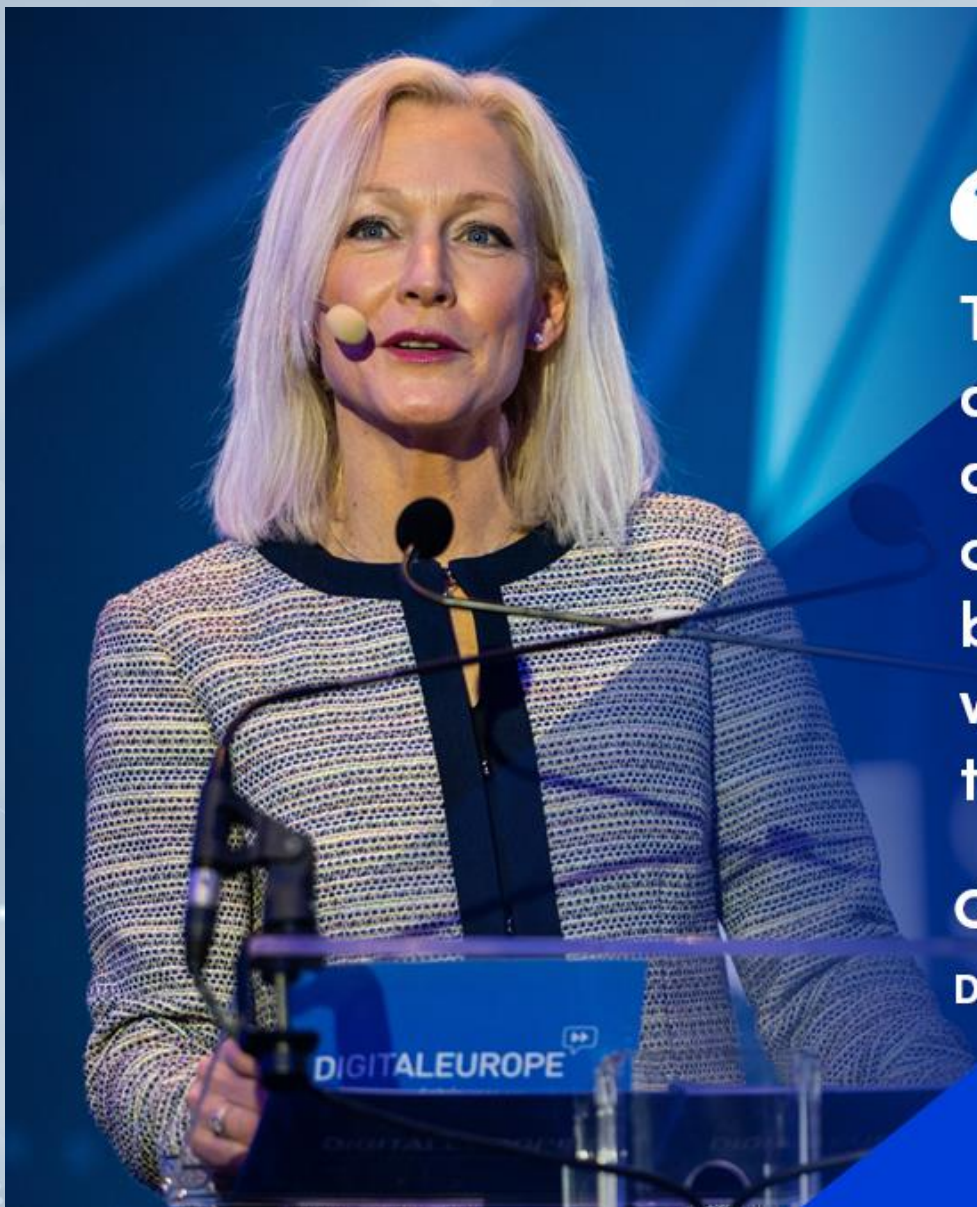
https://www.nature.com/articles/s41746-023-00754-6
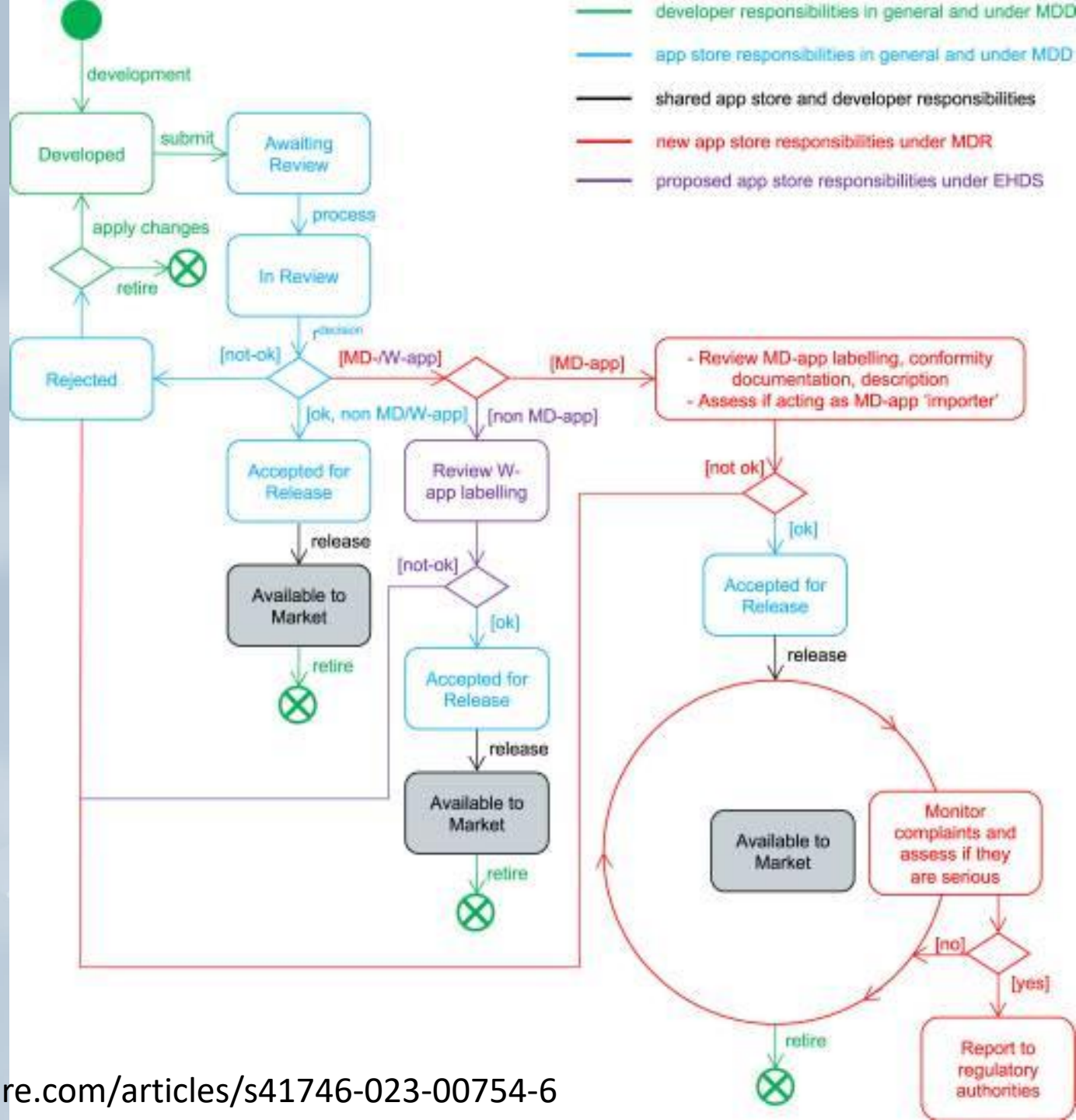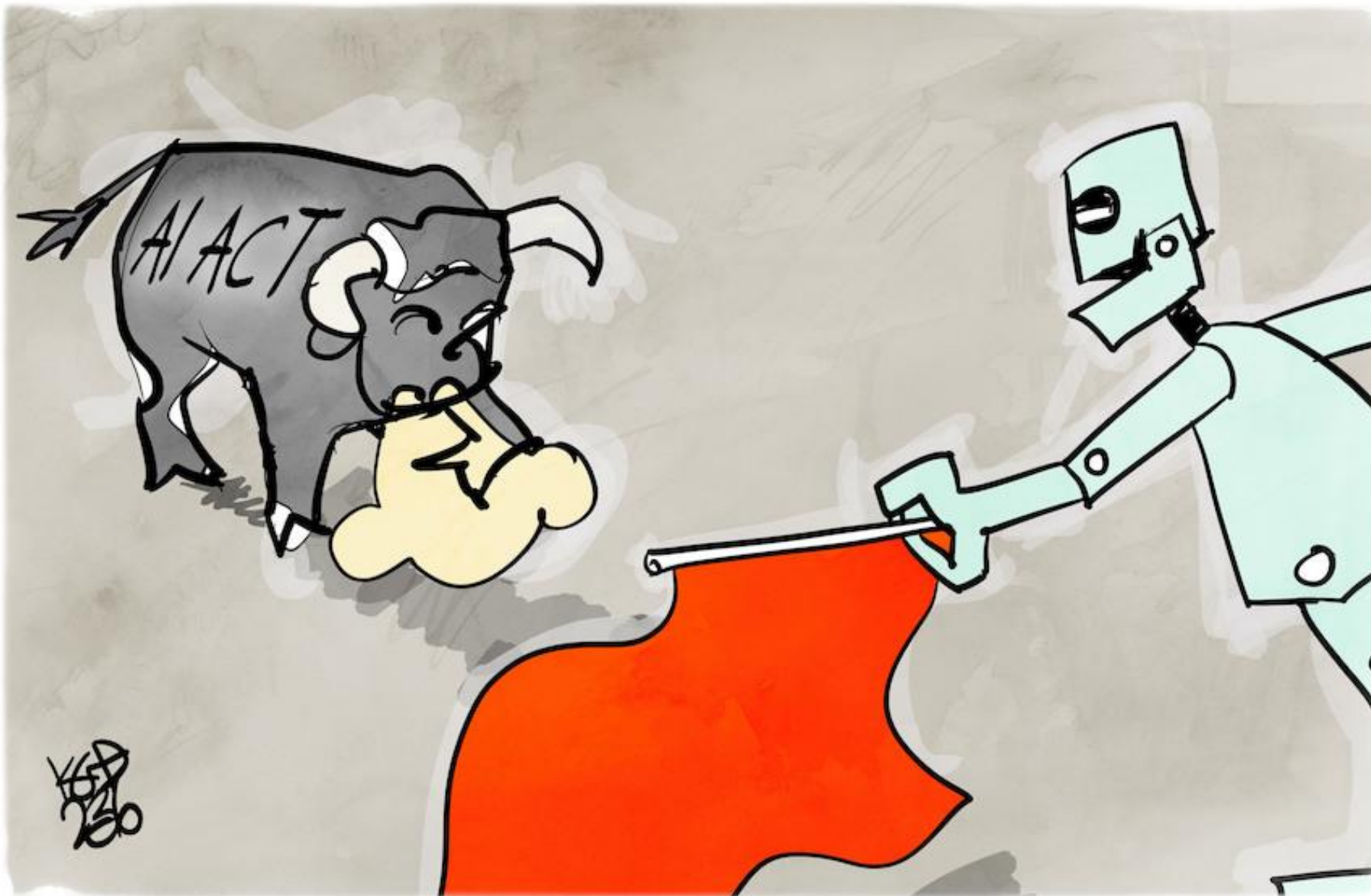
"...FDA has authorized over 690 AI-enabled medical devices... As of October 19th 2023, the FDA has not authorized as a medical device any technology that uses generative AI or LLMs as most medical devices currently approved have "locked algorithms'."

"The biggest challenge with approving GenAI and LLM medical devices is how to provide responsible regulatory oversight to a model that is continuously learning and updating without stifling innovation."

"It can be said that this is the "Wild, Wild West of AI" due to the regulatory oversight not keeping up with the pace of innovation."

LLM – large language models

(2) https://www.himss.org/resources/section-5-navigating-regulatory-landscape-analysis-legal-and-ethical-oversight-large

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> The AI Act is an historic milestone and largely reflects the risk-based approach we called for. We have our concerns, especially on the regulatory burden for SMEs. Now, for Europe to win the global AI race we need to work together to support our innovators.

CECILIA BONEFELD-DAHL
DIRECTOR-GENERAL, DIGITALEUROPE

"EDIHs and TEFs will play a significant role in mitigating the costs of compliance for SMEs when adhering to the AI Act requirements.

Timely involvement of EDIHs and TEFs – through the development of common technological, legal, and management services – is recommended to activate economies of scale and generate cost savings for SMEs when complying with the new requirements. "

https://www.digitalsme.eu/the-ai-act-help-or-hindrance-for-smes/

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Testing and Experimentation Facilities for Health AI and Robotics

For Producers of AI solutions
(start-ups, SMEs, industry)

Access to 50+ leading Hospitals, Medical Universities, certification bodies.

Test AI Solutions in large-scale real –or realistic- environments

Receive **funding** (total 30M€ as reduction in fees)

Support in **market access** for intelligent technologies

Close the gap in AI Innovation Chain

Grow and scale
Validate AI solutions in real health environments

Match & connect
Facilitate market access for AI solutions in health

Train and Attract
Upskilling in Health AI for entrepreneurs & professionals

For Providers of facilities
(Hospitals, R&D Centers)

Access to 1500+ international start-ups, SMEs

Privileged and early **access to AI solutions** as well as data networks

Receive **funding** (total of 30M€)

Optimize investments and avoid duplication of facilities

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TEF-Health: consortium

- Partners
- State of Berlin
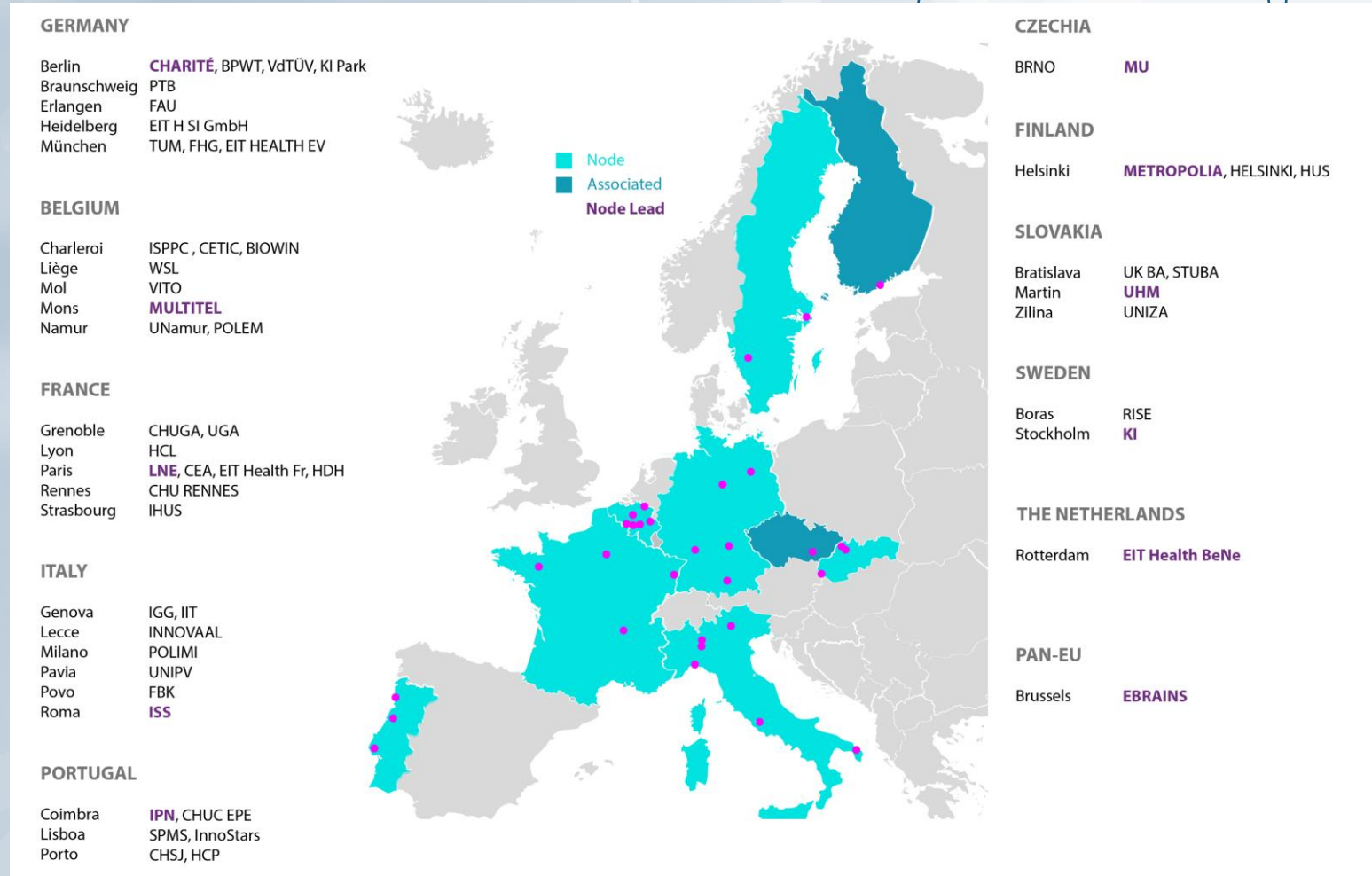(Senate Dept. Economics)

- Partners
- Wallon gouvernement

- Ministère de l'économie
(acceleration AI strategy,
eHealth strategy)

- Partners

- IAPMEI (Agency for
competitiveness and
innovation)

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

Node
Associated
Node Lead

CZECHIA

| BRNO | **MU** |

FINLAND

| Helsinki | **METROPOLIA**, HELSINKI, HUS |

SLOVAKIA

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

SWEDEN

| Boras | RISE |
| Stockholm | **KI** |

THE NETHERLANDS

| Rotterdam | **EIT Health BeNe** |

PAN-EU

| Brussels | **EBRAINS** |

- Government

- Minister of
investment,
regional devt.
& information

- Vinnova
(Government)

Co-funding (MS)   Partners

Lead: **Charité-BIH**, Berlin, Germany

Testing and Experimentation Facilities (TEF) for Health AI and Robotics

Objectives

1.
Validate AI solutions in real health environments

2.
Facilitate **market access** for AI solutions in health

TRL 4 TRL 5 TRL 6 TRL 7 TRL 8 TRL 9

Physical and Virtual testing services

Certification Support Services

Business Skills

TRL 4 - Validation of the technology in the lab;
TRL 5 - Validation of technology in a relevant environment (semi-industrial);
TRL 6 - Demonstration of the technology in a relevant (semi-industrial) environment;
TRL 7 - Demonstration of the prototype system in an operational environment;
TRL 8 - Complete and qualified system; and,
TRL 9 - Approved system in series production environment.

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TEF-Health Call #1 - Start-ups e PMEs

TEF-Health Pilot Call #1 - Portuguese service providers | 2024

tefhealth.eu/call/call-1

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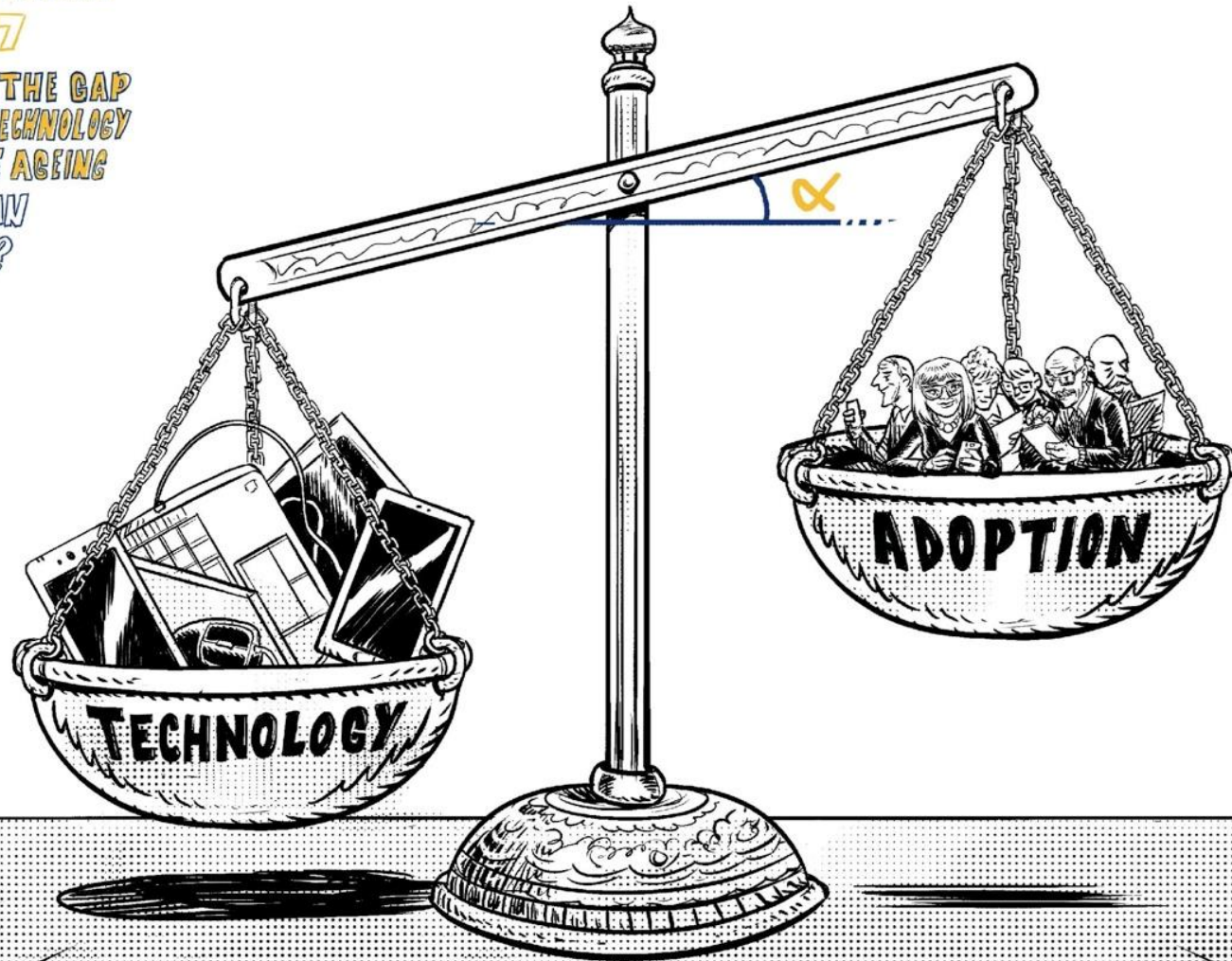
SCRIPT: ANTÓNIO CUNHA ILLUSTRATIONS: ANDRÉ CAETANO

Obrigado

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