When does a patient become a person?

The regulatory framework: a complex but necessary layer

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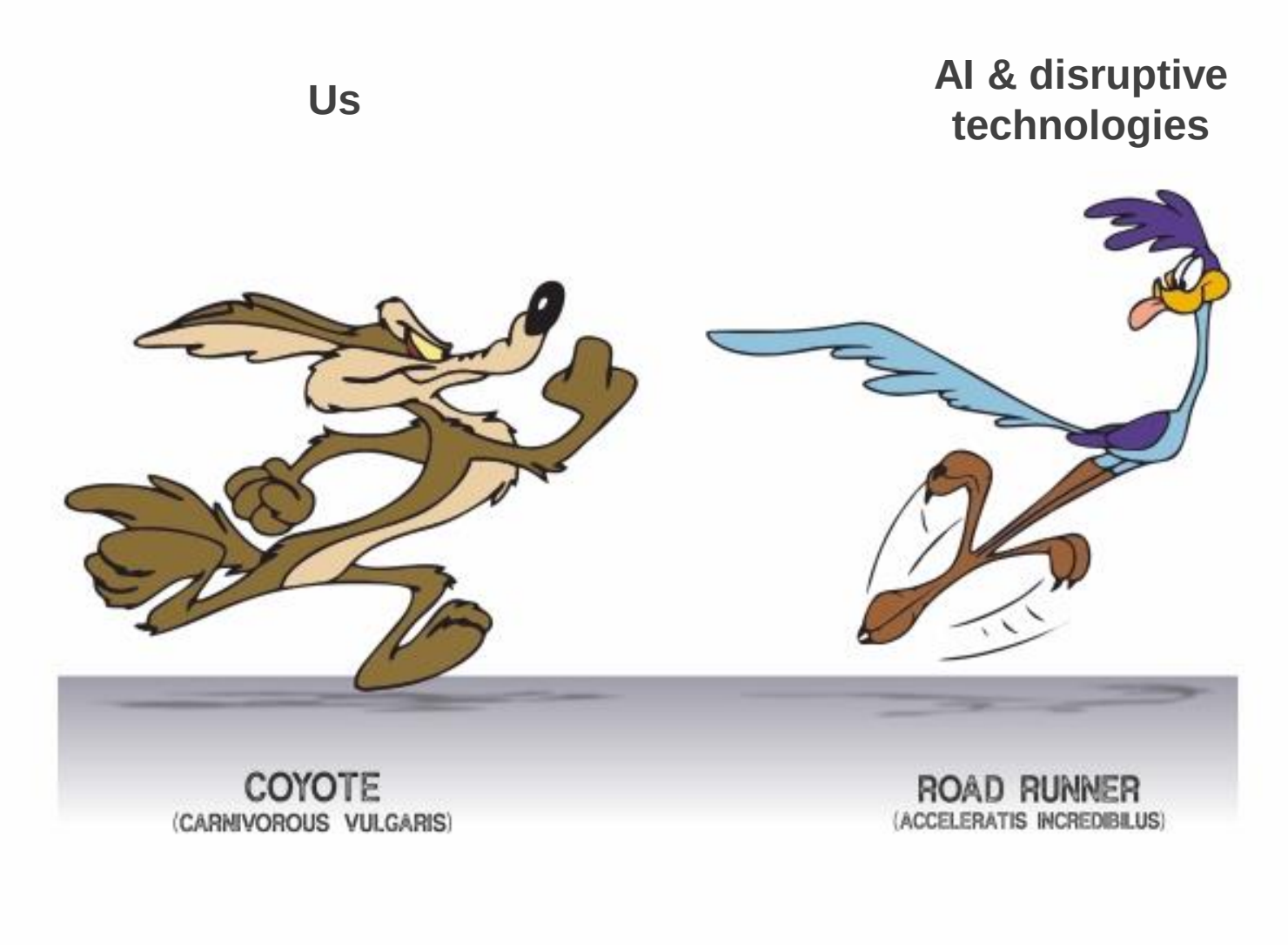
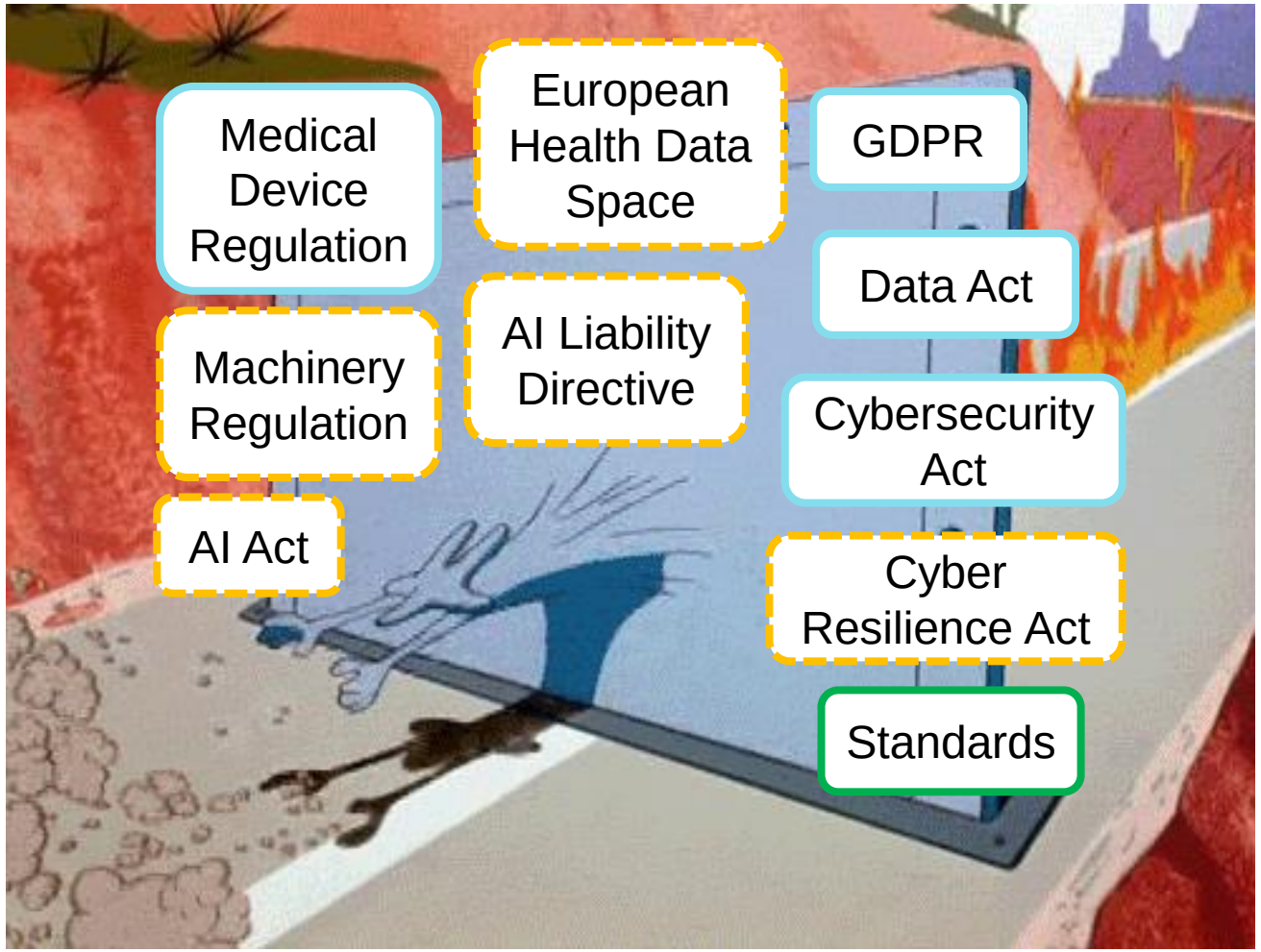
Innovation is fast and we are chasing it



Some challenges along the way…

The regulatory framework

Innovative, technology-enabled solutions need to be regulated for safety and quality.



Harmonised legislation

“New Legislative Framework”: establishes a common legal framework for families of products based on **essential safety requirements** to enter the market.
It defines common terms and procedures (e.g. conformity assessment, CE marking, market surveillance) to allow future legislation to be **more consistent** and easier to implement.

26 EU legal acts aligned with it (“**harmonised legislation**”), including Medical Device Regulation and Machinery Regulation.

The AI Act is also based on this framework

- ✓ Essential safety requirements with risk-based approach
- ✓ Lifecycle approach (pre- and post-monitoring)
- ✓ Conformity assessment and CE mark
- ✓ **Complementarity** with other legislation

CE

Why complementarity is needed

Digital health solutions are often the **combination** of existing and new components, devices or software. This is a regulatory challenge, because the components can **fall under different laws**.

E.g. telerehabilitation

SOFTWARE PLATFORM

MDR
GDPR
EHDS

HARDWARE

CE mark as general consumer product

ELECTRONIC HEALTH RECORD

GDPR
EHDS
Cyber Resilience Act

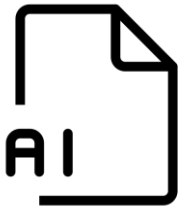
MEDICAL DEVICES

MDR
GDPR

WEARABLES/APPS

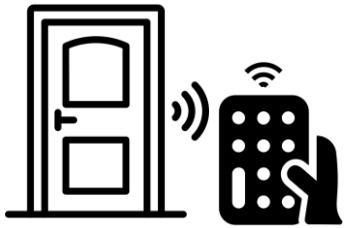
CE mark as general consumer product (or MDR)
GDPR
Cyber Resilience Act

AI



AI Act
GDPR
(MDR)

SMART HOME & AT

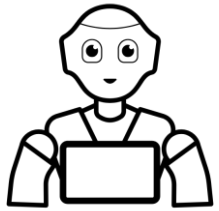


Cyber Resilience Act
CE mark as general consumer product

VIRTUAL REALITY

CE mark as general consumer product

CARE ROBOTS



Machinery Regulation
AI Act

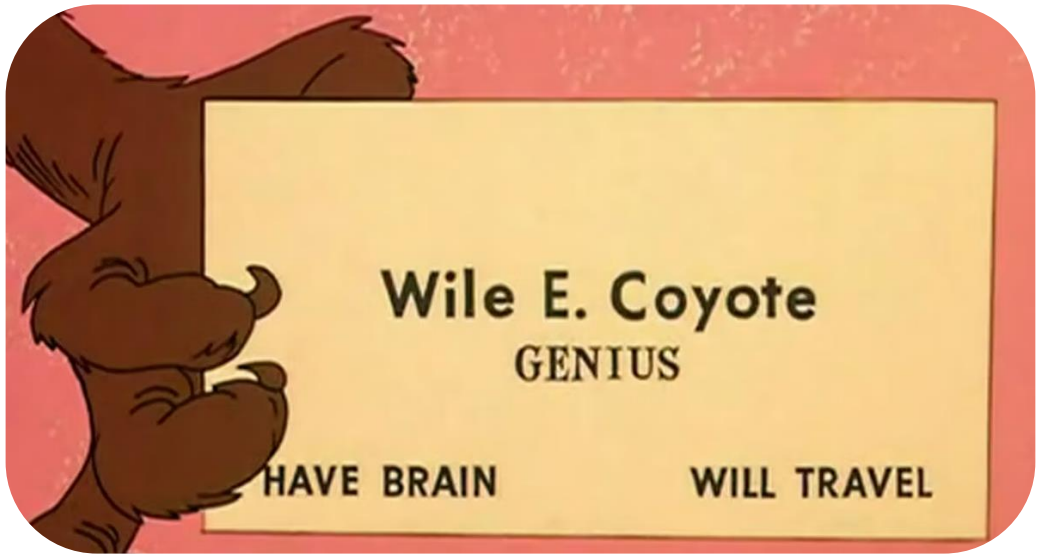
Harmonised legislation means…

An agile approach:

- Avoiding duplications and waste of resources through common procedures
- Single conformity assessment and certification (e.g. a manufacturer of an AI-based medical device will do a single assessment covering both the MDR and AI Act)
- European harmonised standards and presumption of conformity (currently working on AI standards for AI Act, deadline spring 2025)

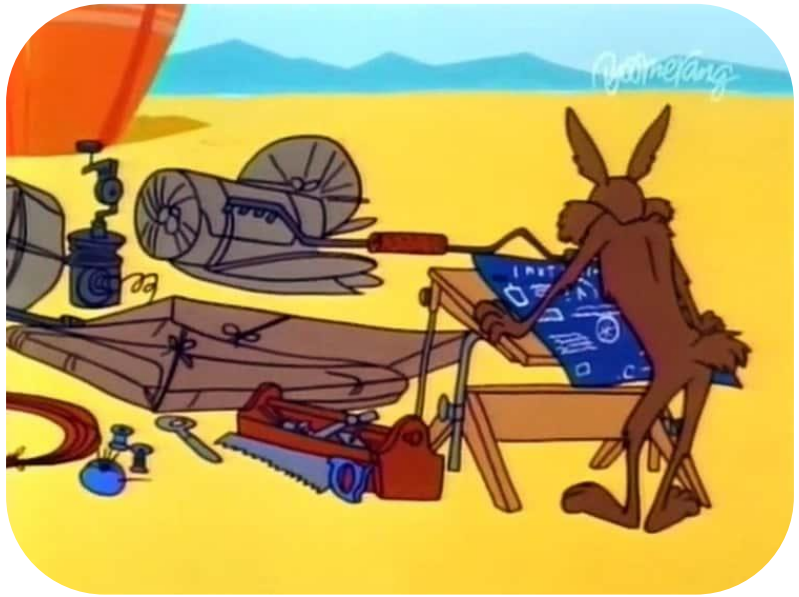
CEN CENELEC ETSI

EUROPEAN STANDARDS ORGANIZATIONS



From theory to practice

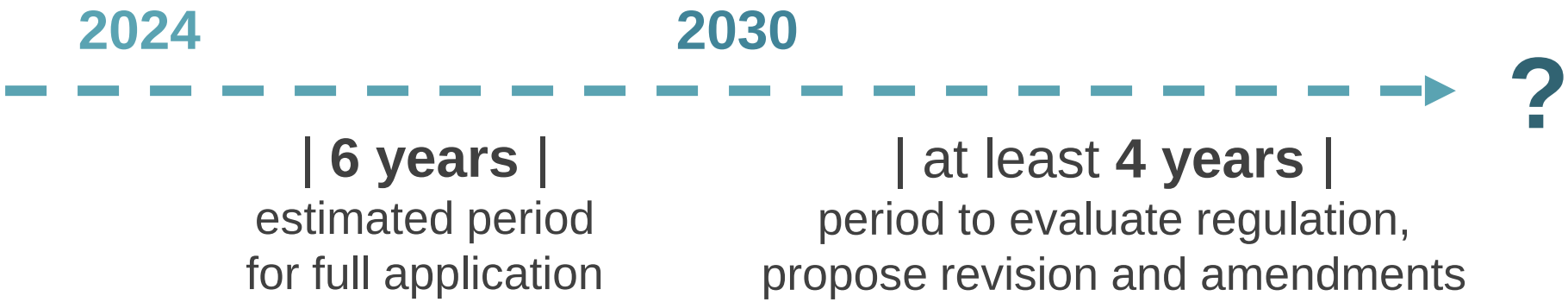
- Framework difficult to navigate for companies
- Conformity is still time-consuming and expensive
  - ~ 300€/hour for technical documentation assessment under MDR
- EU harmonised standards for some technologies still in development
- General-use products that are part of digital health solutions but are not regulated as medical devices: how do we manage them?
  - e.g. wearables, VR glasses, wellness apps, care robots



Still running behind

The “pacing problem”: legislation (especially binding laws) is slow compared to technological developments

Example: AI Act timeline



Meanwhile, AI will evolve in ways that are still **unknown** to us

Thank you

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Group discussion

4 groups, each discussing one of the following questions:

1. When does a patient become a person?
2. How can AI and technology enhance our sense of community?
3. How can AI and technology enhance rehabilitation services integration?
4. How can we help AI to become helpful?

Time: 20 min