#### We represent over 36,000 businesses across Europe

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# The voice of digitally transforming industries

- pharmaceutical businesses,
- medical devices manufacturers,
- tests and vaccine
  telecoms, developers,
- consumer healthcare,
- insurance companies,

# DIGITALEUROPE

- platform services,
- data analytics,
- software,
- hardware,
- semiconductors,
  - cloud technology

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## **Towards the Digital Health Decade**

# DIGITALEUROPE





**Continuity and personalisation** Seamlessly connected tech Remote where best suited



Virtualisation

Optimising invasive procedures Test and devices & medicines



**Precision** Omics and genetics Cell and gene therapy





Demonstrate benefits



Leveraging existing successes



Privacy & security by design



Patient-centric services

## Unlocking the value of health data at scale



#### Governance

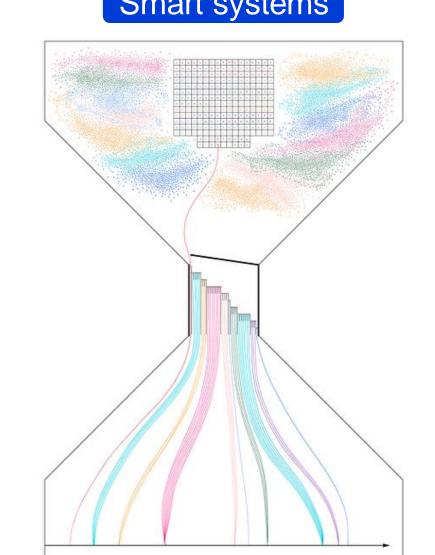


**Secure EHRs Remote & personal** digital services





- thriving data economy
- Harmonisation of privacy rules
- **Single market for** digital health and data
- **Enable R&I Standardisation** Investment & support **Optimal security**



#### Smart systems

### Real life use

#### Improved Patient Experience

#### Reduce healthcare costs

#### Improved clinicians experience

#### **Better outcomes**

Credit: Stefanie Posavec



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Chapter III

#### Use of interoperable Electronic Health Records across Europe

- Patients' rights for access, control
- Telemedicine
- EHR systems self certification + medical devices and Al
- Wellness apps label

## Re-use of quality health data for re-use across Europe

- Common data types, purposes, fees and processes for permits
- **Sharing obligation** in case of permit
- Metadata standards & catalogues
- Secure environments

#### Secondary use

**Primary use** 

Health IT

Patient facing tools

EU-infrastructure

EU-infrastructure

Clinician support

- Regulatory
- Policy
- R&D (pharma & MDs)
- Al

Chapter IV

#### EHDS initial reactions





#### Secure EHRs Remote & personal digital services



Patients' rights Governance for thriving data economy



Harmonisation of privacy rules Single market for digital health and data



Enable R&I Standardisation Investment & support Optimal security









#### **Our 7 suggestions for improving the text**

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- 1. Reduce complexity: clear delineation and interplay GDPR & medical regs
- 2. Create clarity for "data holders": ambiguous but farreaching impact
- 3. Enable useful data analysis: use-case driven governance
- 4. Ensure proportionate EHR systems' certification: targeted scope needed

- Streamline health data sharing and access: procedures and fee structures should be fair
- 6. Enable the global endeavour of innovation and R&D: aligned standards for interoperability & a clear legal framework for international data flows
- 7. Make the EHDS and its Board inclusive: Key stakeholders to be engaged, including innovators.