

# Health data: Opportunities for medical technology companies

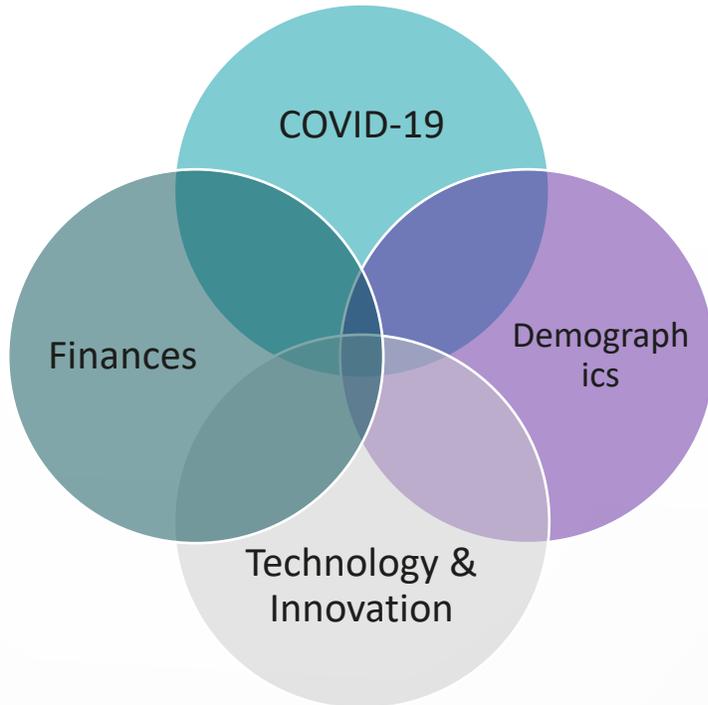
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**beMedTech & i~HD Health Data Quality Seminar  
17 May 2022**

# Health data and the EU policy context

# Where are the opportunities from data?

## Challenges facing societies



Opportunities from data and digital health

## Challenges for health authorities



# Digital health is transforming healthcare practice

Connectivity enables virtual interaction ...

Care search & scheduling



Telehealth



... allowing **remote monitoring**, real-time **self-help** and **proactive care**



**Big data** enables real-time analytics

Clinical decision support



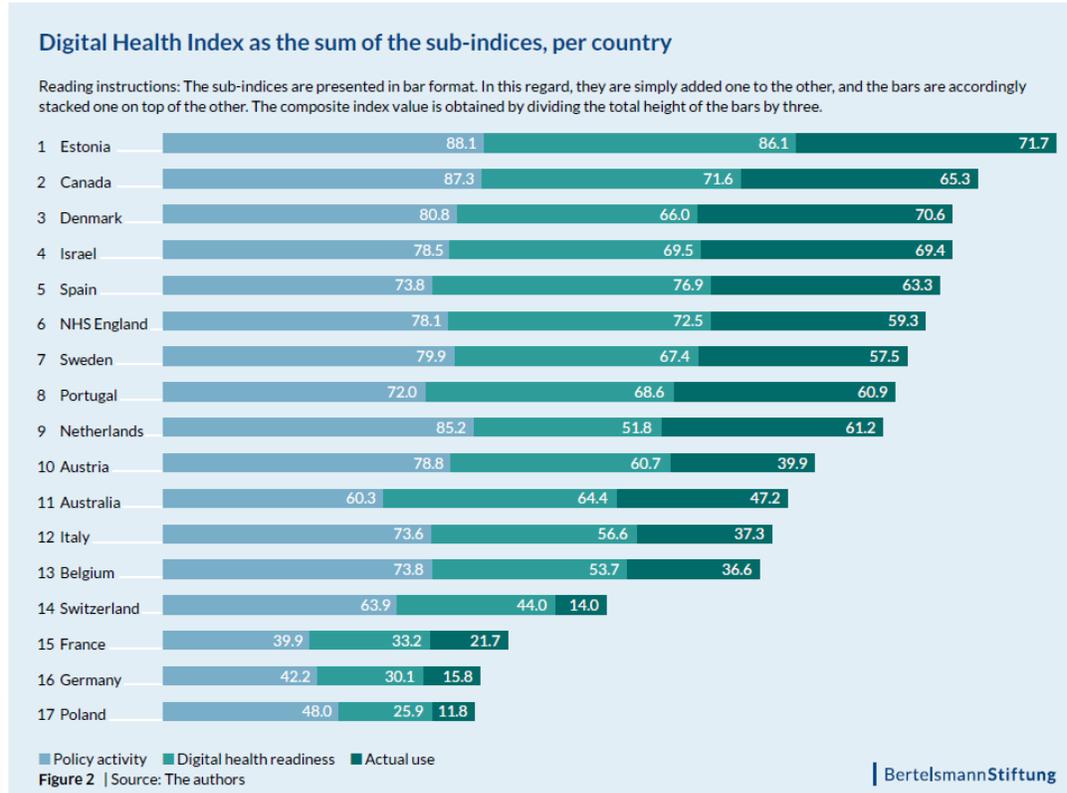
Clinical research



**Automation** improves patient experience, outcomes and provider efficiency



# Uneven levels of digital health deployment



- Disparities in European Member States
- Fragmentation of the digital single (health) market
- Lack of European coordination

#SmartHealthSystems: International comparison of digital strategies, Bertelsmann Stiftung, 2019  
<https://www.bertelsmann-stiftung.de/en/publications/publication/did/summary-smarthealthsystems-focus-europe>



*“We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote **health-data exchange** and support research on new preventive strategies, as well as on **treatments, medicines, medical devices and outcomes**. As part of this, you should ensure **citizens have control** over their own **personal data**.”*

*Mission letter of Commissioner for Health (December 2019)*

# 19 February 2020: Data strategy for Europe

- Assertion of European data sovereignty
- Commitment to European data spaces
- Rules covering cross-border data use, data interoperability and standards
- Up to €6 bn investment in infrastructure

## A common European Health Data Space (EHDS)



Thierry Breton  
@ThierryBreton

The battle for industrial #data starts now, and the main battlefield will be Europe 🇪🇺

Europe is the world's top industrial continent.

We will organize ourselves to win this battle.  
#MSC2020 [reuters.com/article/us-eu-...](https://reuters.com/article/us-eu-...)



Europe can win global battle for industrial data, EU industry c...  
Europe may have lost the battle to create digital champions capable of taking on U.S. and Chinese companies harvesting personal data, [reuters.com](https://reuters.com)

487 5:05 PM - Feb 15, 2020

250 people are talking about this

# The EU digital and data legislation landscape

## GDPR

Protect natural persons regarding the processing of personal data and on the free movement of such data

## Data Governance Act

Aims to increase trust in data intermediaries, strengthen data-sharing mechanisms

## NIS2 Directive

Strengthen cyber security requirements, address security of supply chains, streamline reporting, more stringent supervision

## Data Act

Regulate B2B and B2G/G2B data sharing

## Product Liability Directive & civil liability rules for AI

Adapting rules on liability to account for developments in circular and digital economy as well as AI technology

## e-Privacy Regulation

Introduces stricter rules for e-communications data, including content, metadata (e.g. location) & device information

## European Health Data Space Legislation

Establishes health data governance rule, promotes exchange of patient data, access to & use of health data for research

## AI regulation

Framework to govern the use of AI to prevent potentially harmful applications

## Cyber Security Act

Establishes cybersecurity certification framework for products and services

- Adopted
- Proposed
- Expected (2022)

# Primary and secondary use of data

# European Health Data Space (EHDS)

## OBJECTIVES

Effective use of health data

## SCOPE & EXPECTED IMPACT

Use of health data  
(primary,  
MyHealth@EU)

- Empower individuals to control their data
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps
- European Electronic Health Record Exchange Format

Single market for health data, data protection, free movement of people, digital goods and services

Re-use of health data  
(secondary,  
HealthData@EU)

- Health data access bodies
- Purposes for use and forbidden use
- Data permits, secure environments, no identification

Facilitated Research & Innovation

Better Policy Making

## MEANS

Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation (MFF)

# How medical technology companies use health data

# How medical technology companies use health data

- MTE position on health data use (June 2021)
- Examples of data use cited:
  - Patient self-management and empowerment
  - Remote patient monitoring
  - Monitoring device performance
  - Data analytics
  - Towards data-driven healthcare
- **Recommendation:** address legal barriers



# Examples of data use

- **Diabetes self-management**

Sensors and algorithms can assist people with diabetes with blood sugar management and calculate and deliver appropriate insulin doses at the appropriate time

- **Hypotension management during surgery**

Technology that provides clinicians with information if a patient trends towards a hypotensive event

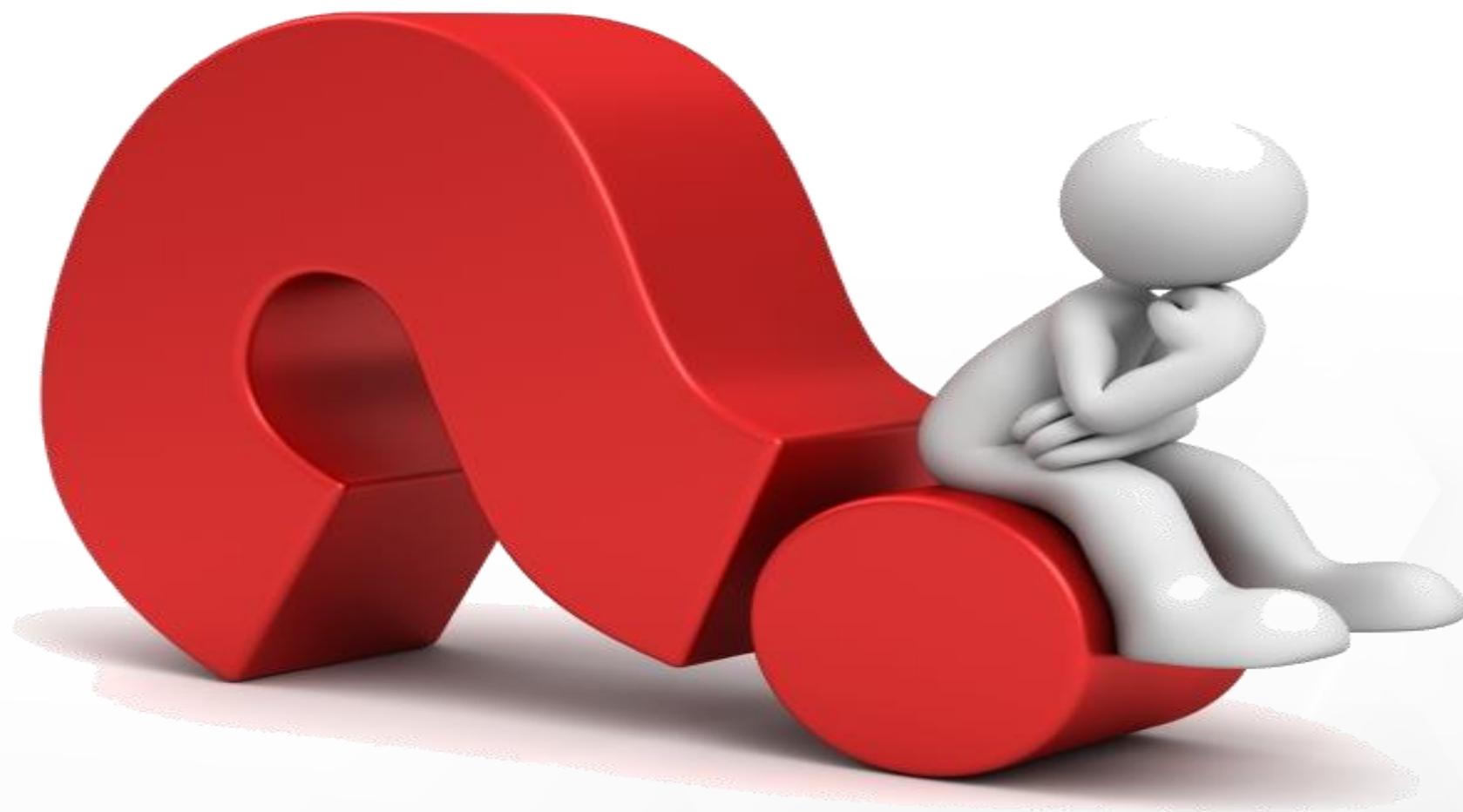
- **Fall prediction**

Data collected through sensors monitoring seniors living independently, analytics that identify patterns, and algorithms that can predict falls





Health data sharing  
brings essential insights  
to solve the health  
problems of tomorrow.



# Thank you!

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