Digitalisation and Data Management

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Towards a European Health Data Space (EHDS)

▶ **OBJECTIVES**

> **Timely and simplified *exchange of* and *access to* health data**

▶ **SCOPE & EXPECTED IMPACT**

Use of health data (primary, EHDS1)	• **Individuals to access and control their data & exchange of health data** (incl. cross-border), irrespective of source (electronic health records, tele-health, m-health, wellness apps)	→ **Single market for data, data protection, free movement of people, digital goods and services**
Re-use of health data (secondary, EHDS2)	• **Research, innovation**	→ **Facilitated Research & Innovation**
	• **Policy (**incl. e.g. public health, HTA**) & Regulatory decisions**	→ **Better Policy Making**

▶ **MEANS**

Legal / Governance	**Quality of data**	**Infrastructure**	**Capacity building / digitalisation (MFF)**

EHDS: What are the problems?

Use of health data for healthcare (primary)

Sharing of health data for healthcare

- **Limited** control to and access to patients
- **Insufficient** exchange of health data
- **Limited** interoperability between health care providers

Single market for digital health products and services

- Uneven national **legislative frameworks**
- Uneven **quality / interoperability** frameworks
- Uneven **procedures** for prescriptions, reimbursement, liability

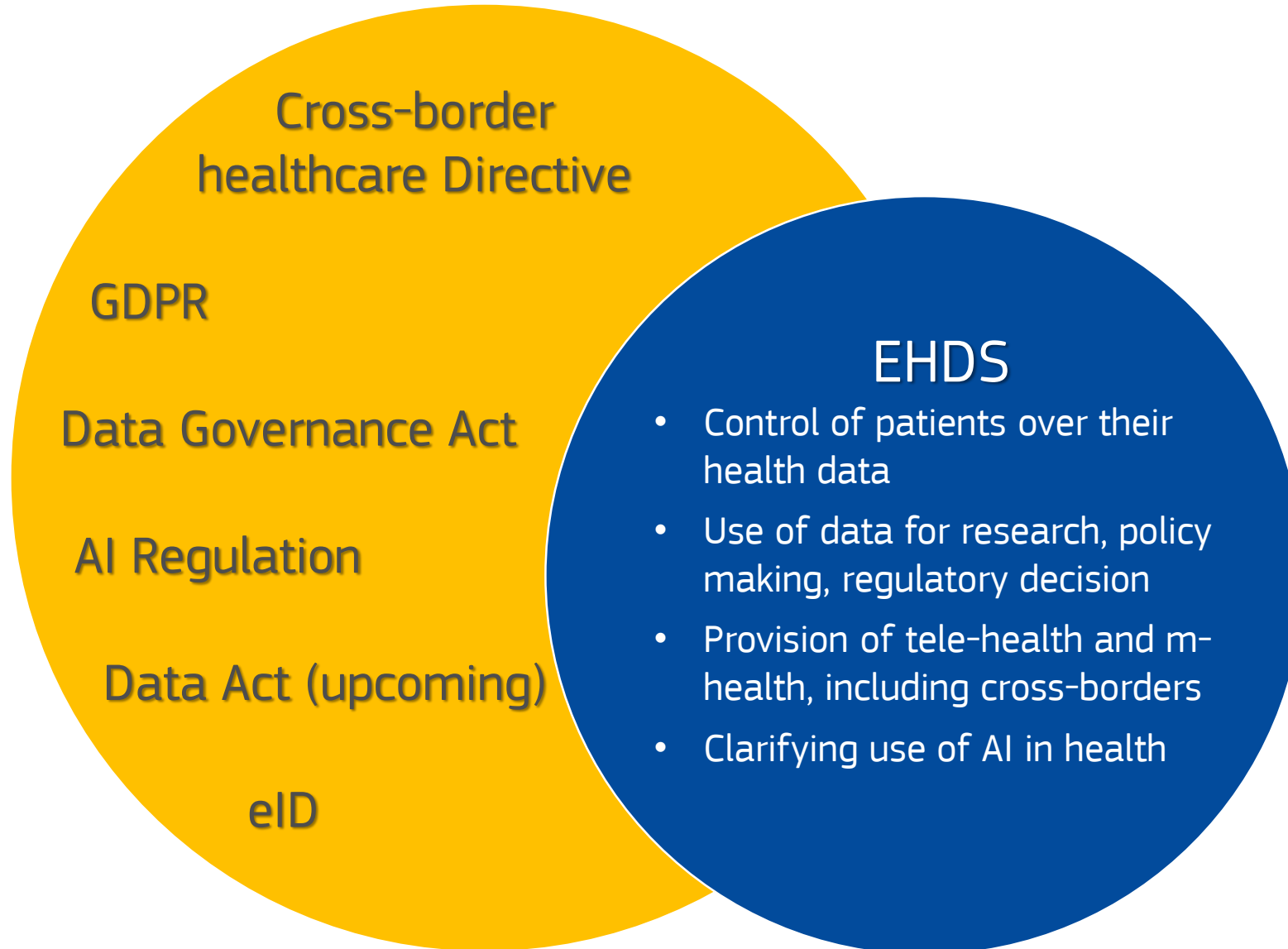## Re-use of health data (secondary)

Research, innovation, public health policy making

- **Low re-use** of health data
- **Cumbersome** cross-border access to health data
- **Fragmented** digital infrastructures

Artificial Intelligence

- **Limited** provision of data for training of AI
- **Difficulties** for regulators to evaluate
- **AI algorithms**
- **Uncertainty** on AI liability in health

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3

EHDS: Articulation with EU regulatory framework

Cross-border healthcare Directive

GDPR

Data Governance Act

AI Regulation

Data Act (upcoming)

eID

EHDS

- Control of patients over their health data
- Use of data for research, policy making, regulatory decision
- Provision of tele-health and m-health, including cross-borders
- Clarifying use of AI in health

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Primary use of health data

General Healthcare: EHDS1 / MyHealth@EU

Rare Diseases: New CPMS

EHDS1: Commission Recommendation on a Electronic Health Record Exchange Format

Initial health information domains:

- patient summaries
- ePrescriptions
- laboratory reports
- medical images and reports
- hospital discharge reports

Interoperability specifications

- **HL7 CDA**
- **DICOM**
- **IHE profiles**

Incremental and selective approach

- adopting, refining, and maintaining the specifications of the European EHR exchange format

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EHDS1: MyHealth@EU
Cross-border exchange of patients' data

- Patient Summaries and ePrescriptions: 9 MS live, more MS in 2021

- In 2021: images,
  laboratory results,
  discharge reports;
  access of patients
  to their health data

MS with commitment to set up the NCPeH

Live: PT, FR, MT, FI, EE, CZ, HR, LU, ES

Go-live planned for Q4 2021: PL, NL

Go-live planned for 2022: GR, SE, IE, CY, IT, SI, HU, SK, LT
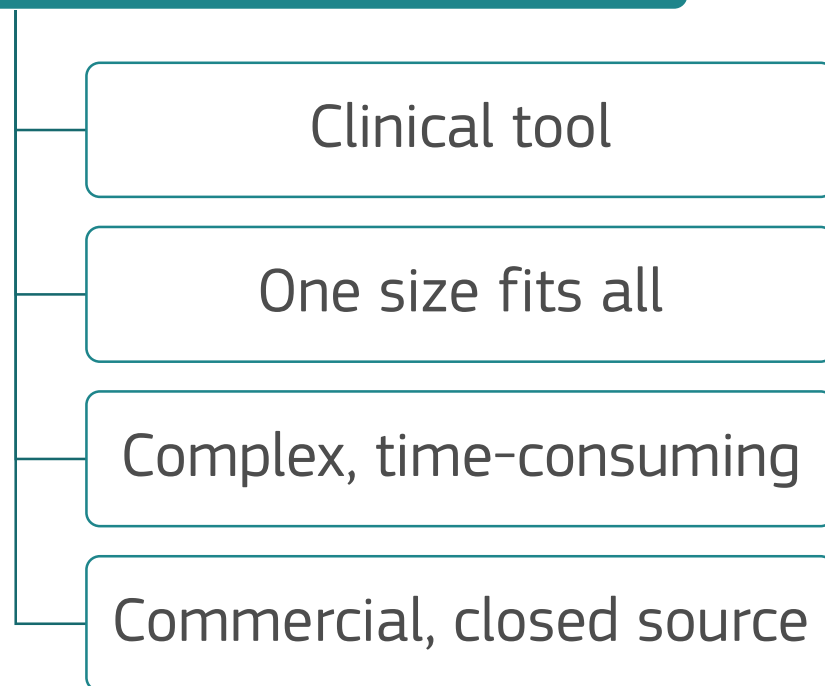
Go-live planned for 2023: BG, LV

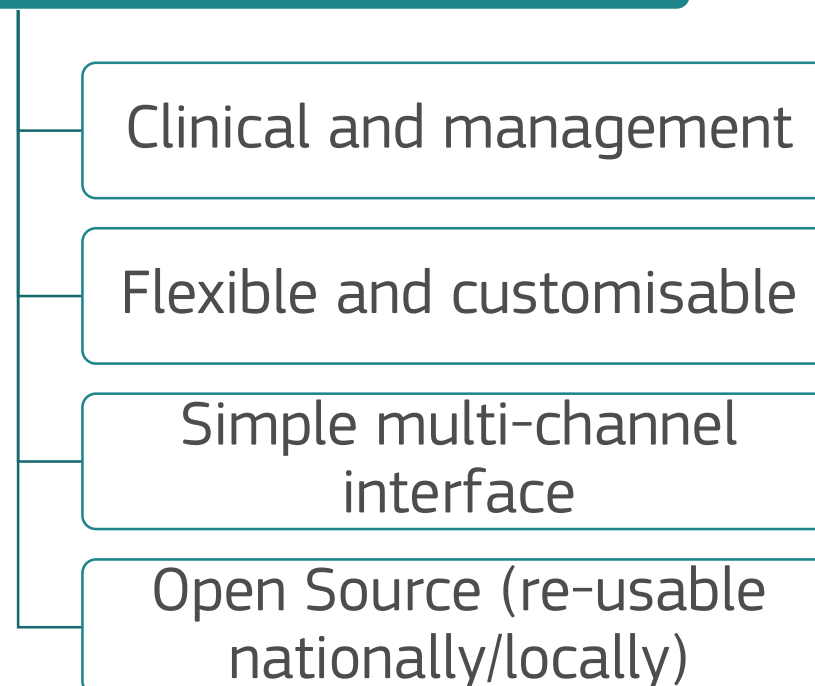**Likeliness of MS to apply to set up the NCPeH**

- **2021: DE, AT, DK, IS**

- 2022-2023: RO

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The New CPMS:
a clinical tool with management features

Current CPMS

- Clinical tool
- One size fits all
- Complex, time-consuming
- Commercial, closed source

The New CPMS

- Clinical and management
- Flexible and customisable
- Simple multi-channel interface
- Open Source (re-usable nationally/locally)

The New CPMS: functionalities for managers

- Configuration panel

- Activity dashboard

  - Consolidated data

  - Past, present and future activities ?
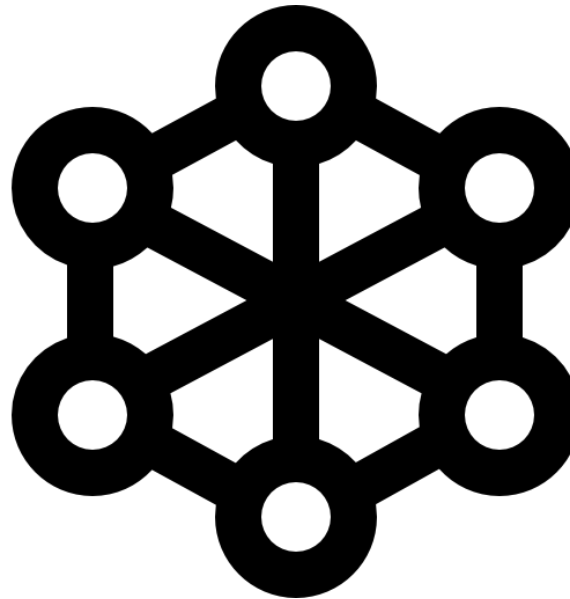
  - Balance sheet ?

Secondary use of health data

General Healthcare: EHDS2

Rare Diseases: ERN Registries

Secondary use of data in the EHDS

Reuse of health data by researchers, policy-makers and industry

Health data from patients and healthcare professionals

Other research data

Rules, protocols, infrastructure and governance

Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format

Pilot project: EHDS2

Targets

2021: Pilot infrastructure

2025: EU-wide infrastructure

Testbed (proof of concept)

Governance

IT and data infrastructure

Demonstrator

Cross-country ecosystem

Secondary use of health data

EU4HEALTH

Pilot project: ERN registries

- Minimum data sets

- EU support: setting up + feeding the registries

- Data from the registries:

  - For research and policy making

  - Available for free/nominal fee to all legitimate actors

  - Access including through data autorisation bodies

Budget

National level investments

- National funds
- RRF
- ERDF
- ESF+
- InvestEU

EU level investments

- EU4Health
- DEP
- Horizon Europe
  (Rare Disease Partnership)

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Thank you!

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Digitalisation and Data Management – Questions

1. Your views on interoperability and digitalisation? Do you plan to use RRF/ERDF or other funds to upgrade your digital systems? What are your main concerns?

2. Do you plan to use Orphacodes? Do you plan to use the ERN registries? How would a new framework for facilitating access to data support research and innovation on rare diseases?

3. Could the New CPMS help on your management decisions regarding ERNs?
    Which decisions? Which information would you need?

4. How could the New CPMS help you in providing support at national level and strengthen the rare disease policy (including in the reimbursement policies)

5. How do you see partly supporting CPMS virtual consultation panels?

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