# THANK YOU FOR JOINING!
The webinar will begin shortly.

# XpanDH Webinar
'Unlocking the Potential: The European Health Data Space and the Digital Future of European Healthcare'

## 16 November 2023 | 14:00 CET

# HOUSEKEEPING

To support the discussion, please only unmute
your microphone when speaking or asking questions.

Our speakers bring a range of expertise and insight.
Please post your question in the Q&A box.

This webinar will be recorded.

# Moderator: Mr Henrique Martins

XpanDH Project Coordinator,
Associate Professor in Health Management and
Leadership at FCS–UBI and ISCTE–IUL

# MEP Tomislav Sokol

Member of the European Parliament, Group of the European People's Party (Christian Democrats)
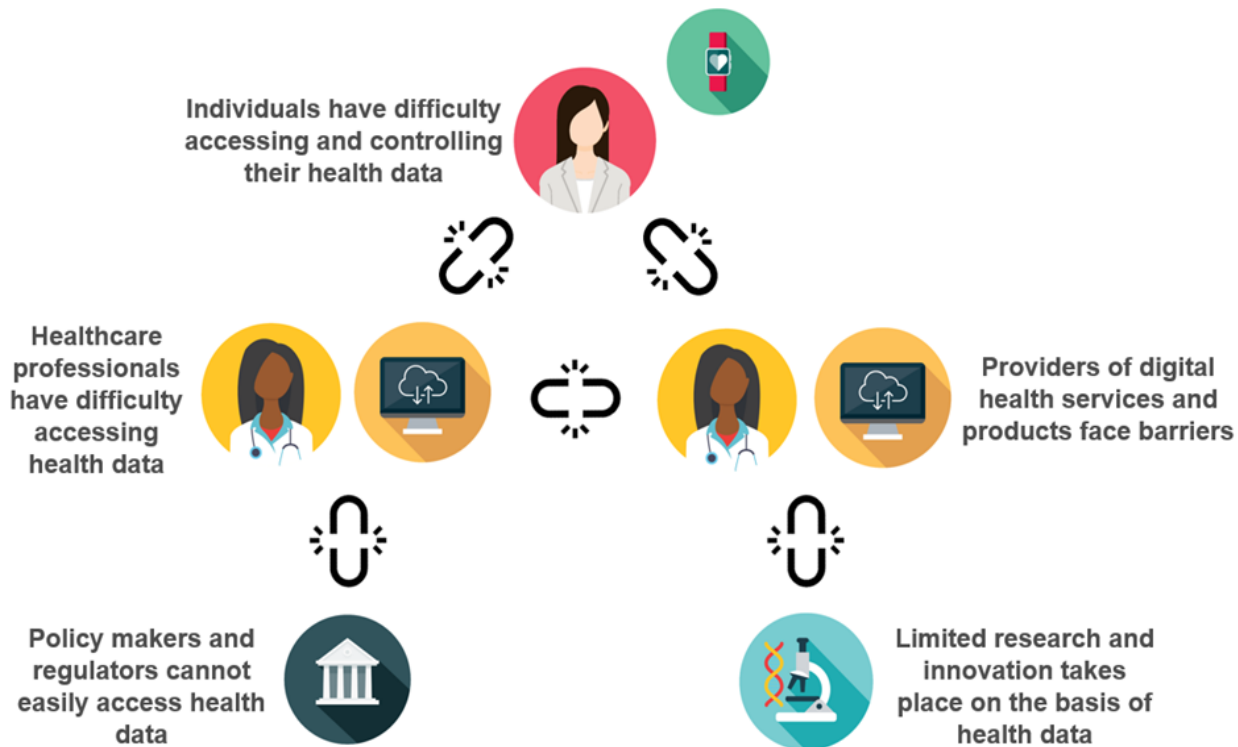
# Dr Konstantin Hyppönen

Policy Officer on digital health at DG SANTE, European Commission

# The European Health Data Space (EHDS) and the role of the European Health Record Exchange Format (EEHRxF) in the EHDS!

**Funded by the European Union**

# Main challenges in harnessing the power of health data



Individuals have difficulty accessing and controlling their health data

Healthcare professionals have difficulty accessing health data

Providers of digital health services and products face barriers

Policy makers and regulators cannot easily access health data

Limited research and innovation takes place on the basis of health data

# EHDS – *the first* sector-specific European Data Space



| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|

**Health** · Industrial & Manufacturing · Agriculture · Finance · Mobility · Green Deal · Energy · Public Administration · Skills

- Driven by stakeholders
- Rich pool of data of varying degree of openness

- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Personal data spaces

High Value Datasets from public sector

## Technical infrastructure for data spaces

Edge Infrastructure & Services · Cloud Infrastructure & Services · High-Performance Computing · AI on demand platform · AI Testing and Experimentation Facilities
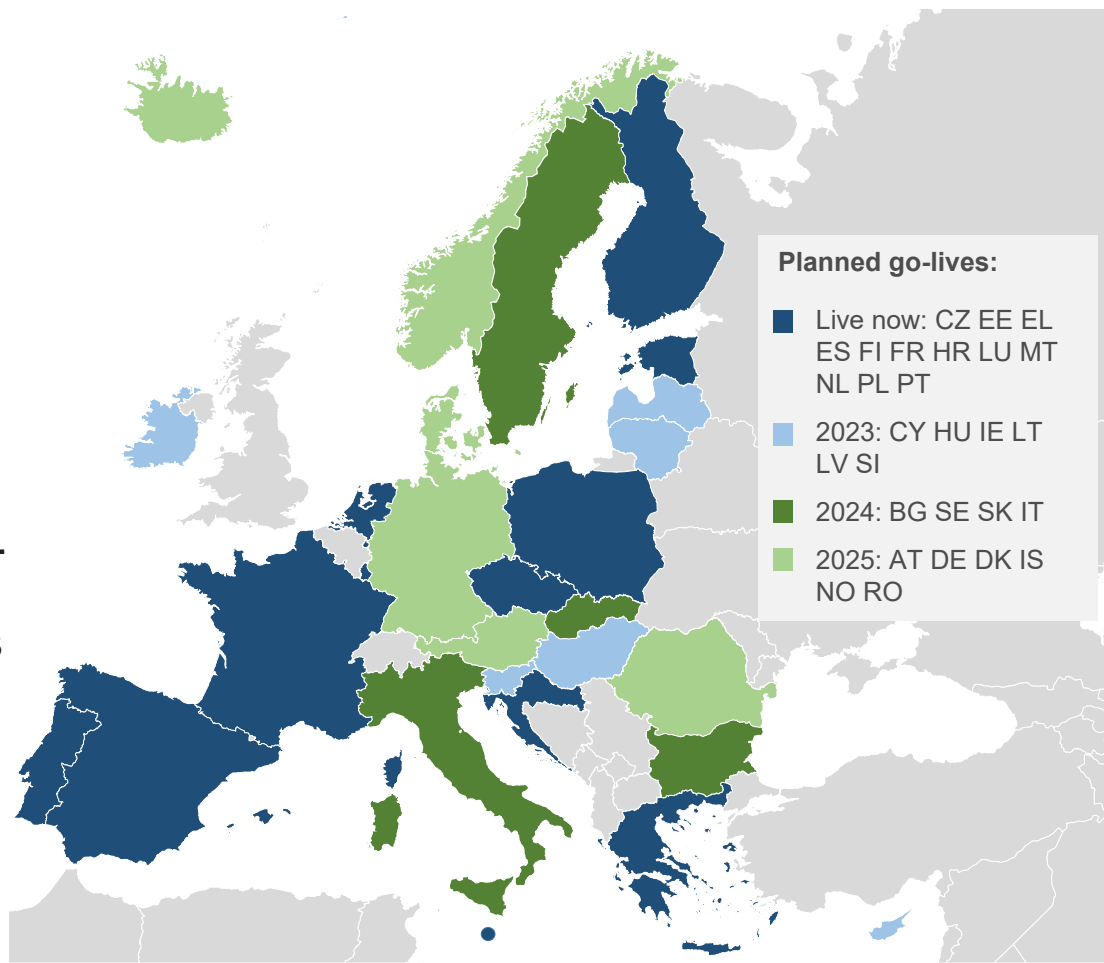
# MyHealth@EU

MyHealth@EU is the existing infrastructure that connects healthcare providers in 12 Member States.

It allows them to exchange health data such as Patient Summaries and ePrescriptions. These services will be expanded to include lab results and other types of health data.

Funded by the European Union

**Planned go-lives:**

- Live now: CZ EE EL ES FI FR HR LU MT NL PL PT
- 2023: CY HU IE LT LV SI
- 2024: BG SE SK IT
- 2025: AT DE DK IS NO RO

# Cross-border electronic prescription in action



Country A

A medicine is prescribed

Electronic prescription

National contact point for digital health

Dispensation details

Country B

Purchase medication in a pharmacy abroad

Take a journey

Show your passport or ID card

Illustration based on materials from: THL/FI

# MyHealth@EU roadmap

**EHDS regulation**

Mandatory participation in MyHealth@EU for all Member States with transitional periods for different services (pending decision by co-legislators)

**Pilot on Patient Access**

PATHeD: enable citizens to access health data in MyHealth@EU (Jan 2023-Jun 2024).

**New services**

Lab results (2025), Medical imaging (2026), Hospital discharge reports (2026), etc.

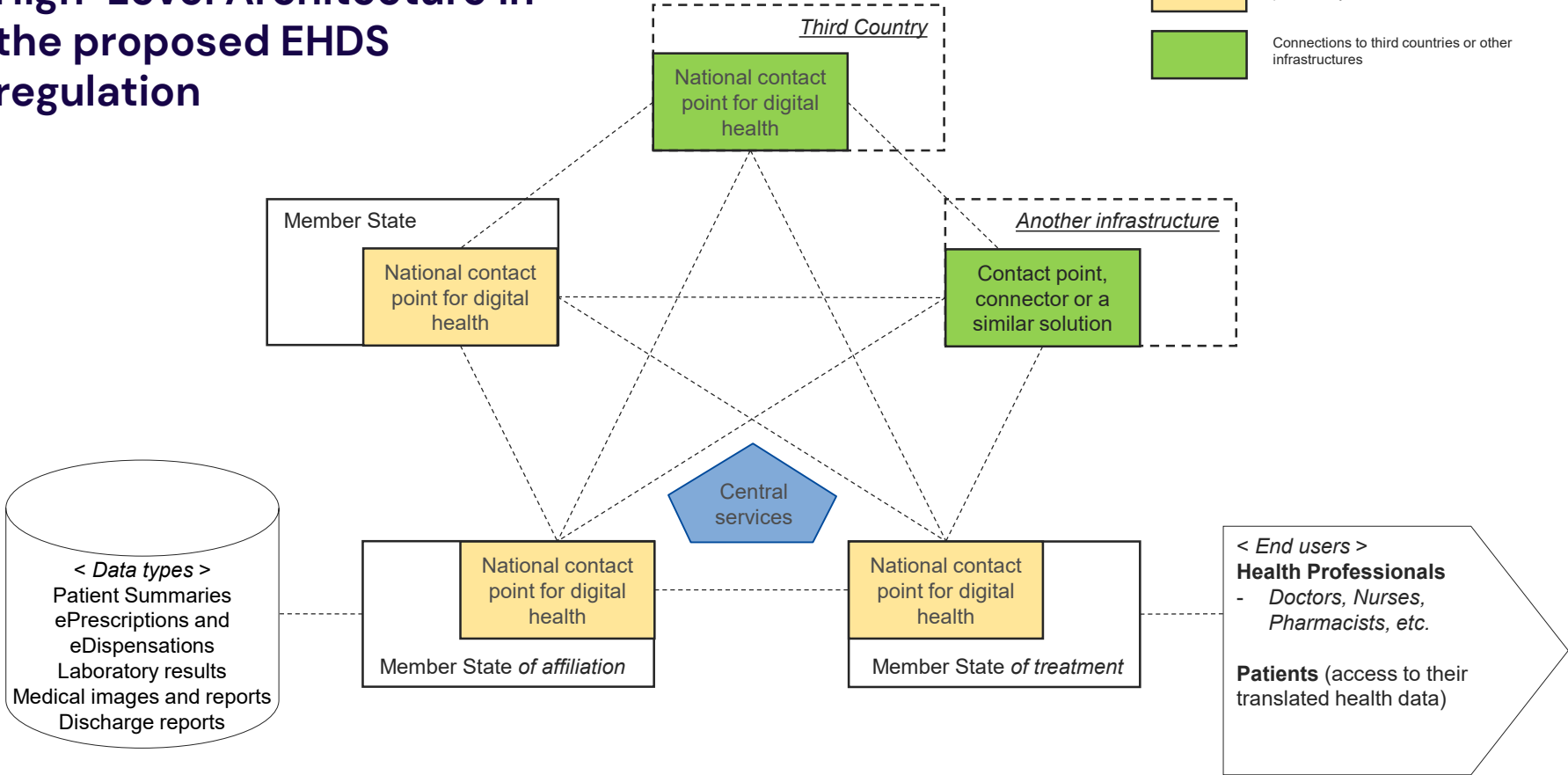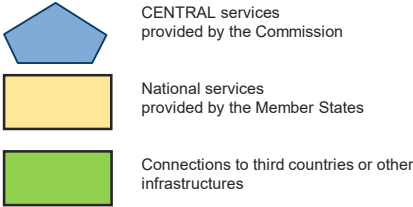**Enhancement of available services using EU Digital Identity Wallet technology**

POTENTIAL Large-Scale Pilot (includes the ePrescription use case)

**New Member States joining MyHealth@EU**

More Points of Care to be connected (2023 and beyond)

# MyHealth@EU High–Level Architecture in the proposed EHDS regulation

CENTRAL services provided by the Commission

National services provided by the Member States

Connections to third countries or other infrastructures

**Third Country**

National contact point for digital health

**Member State**

National contact point for digital health

**Another infrastructure**

Contact point, connector or a similar solution

Central services

< Data types >
Patient Summaries
ePrescriptions and eDispensations
Laboratory results
Medical images and reports
Discharge reports

National contact point for digital health

Member State *of affiliation*

National contact point for digital health

Member State *of treatment*

< End users >
**Health Professionals**
- *Doctors, Nurses, Pharmacists, etc.*

**Patients** (access to their translated health data)

# EHDS proposal *Article 6*

*European electronic health record exchange format*

1. The Commission shall, by means of **implementing acts**, lay down the **technical specifications** for the **priority categories** of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:
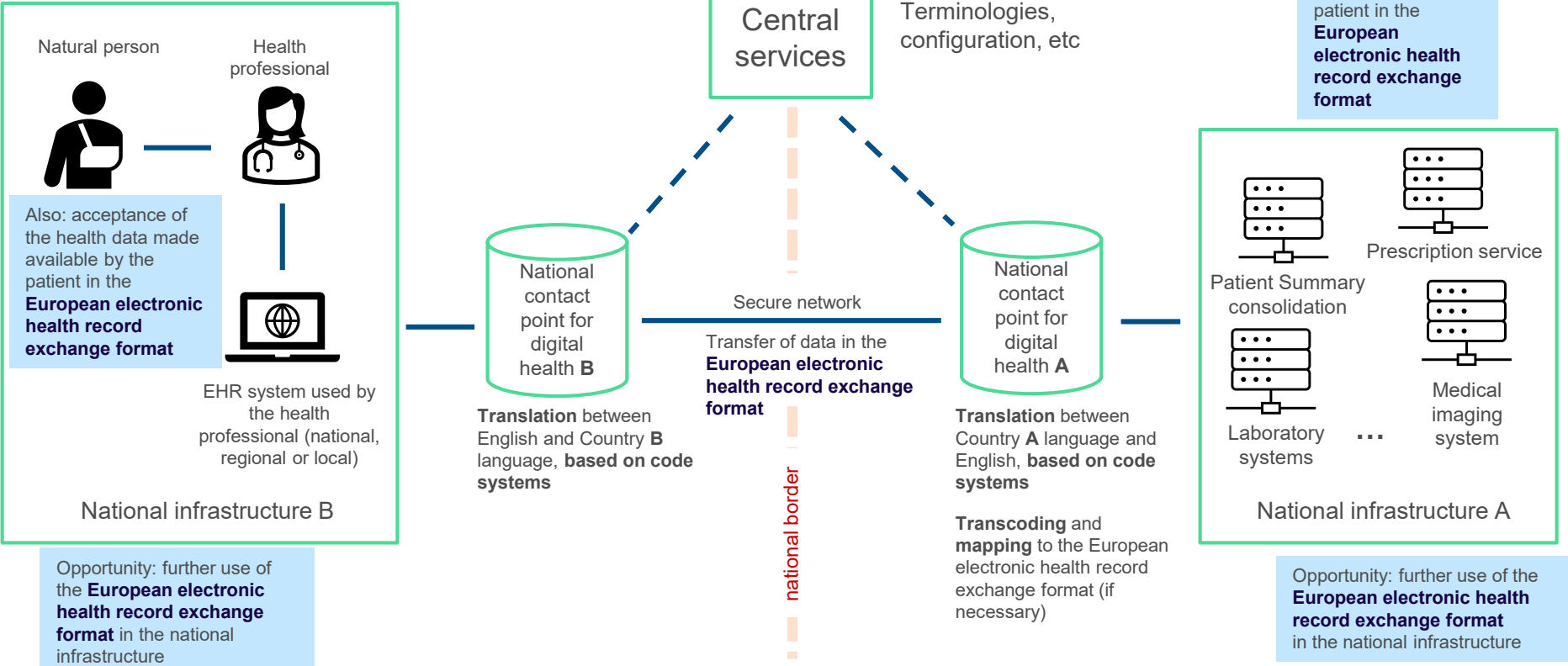
   (a) **datasets** containing electronic health data and defining structures, such as data fields and data groups for the content representation of clinical content and other parts of the electronic health data;

   (b) **coding systems** and **values** to be used in datasets containing electronic health data;

   (c) **technical specifications** for the **exchange** of electronic health data, including its **content representation**, **standards** and **profiles**.

2. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are **provided by a natural person directly** or **transmitted to a healthcare provider** by automatic means in the format referred to in paragraph 1, such data shall be **read** and **accepted** by the data recipient.

3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **issued** in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.

# Cross-border flow of data through MyHealth@EU

Natural person

Health professional

EHR system used by the health professional (national, regional or local)

National infrastructure B

Also: acceptance of the health data made available by the patient in the **European electronic health record exchange format**

Opportunity: further use of the **European electronic health record exchange format** in the national infrastructure

Central services

Terminologies, configuration, etc

National contact point for digital health **B**

**Translation** between English and Country B language, **based on code systems**

Secure network

Transfer of data in the **European electronic health record exchange format**

national border

National contact point for digital health **A**

**Translation** between Country A language and English, **based on code systems**

**Transcoding** and **mapping** to the European electronic health record exchange format (if necessary)

Patient Summary consolidation

Prescription service

Laboratory systems

Medical imaging system

National infrastructure A

Also: issuance of health data to the patient in the **European electronic health record exchange format**

Opportunity: further use of the **European electronic health record exchange format** in the national infrastructure

# Actions related to the European electronic health record exchange format (EEHRxF)

**Innovation, experimentation**

**epSOS, EXPAND, JAseHN, eHAction**
- Development of the MyHealth@EU infrastructure

**X-eHealth**
- Work on lab results, hospital discharge reports, medical imaging
- Defined use cases, data sets, data models
- Implementation guides for CDA and FHIR

**XpanDH**
- Further elaboration of the format
- Pilots, verification of implementability
- Set-up of the ecosystem

**Project(s) under HORIZON 2023: Expanding the EEHRxF to improve interoperability within EHDS**
- Further expansion of the exchange format

**Formalisation**

**Work on the eHealth Network guidelines**
- Use cases, data sets, principles
- Adopted by Member States in the eHN

**Work by MyHealth@EU Solution Provider**
- Implementable specifications, other artefacts
- Implementation in OpenNCP for MyHealth@EU
- Adopted by Member States in the eHMSEG

**Xt-EHR** (Joint Action 09 under EU4Health WP2022)
- Work on the formalisation of the format
- Requirements for the certification of EHR systems
(recommendations for possible future implementing acts under EHDS)

**Implementing Decisions under the upcoming EHDS**
- Legally binding requirements and specifications for the European health record exchange format
- Legally binding requirements for the certification of EHR systems

**Infrastructure, deployment**

**MyHealth@EU current and future services**

**Patient Summary and ePrescription**
- HL7 CDA for structured content
- PDF available (except eDispensation)
- IHE XDS profiles for content transmission

**Original Clinical Documents**
- HL7 CDA header, no further structured content
- PDF for content representation
- IHE XDS profiles for content transmission

**Lab results, hospital discharge reports, medical imaging**
- To be based mostly on HL7 FHIR
- DICOM for medical imaging studies

**Further data categories**
- Not defined yet

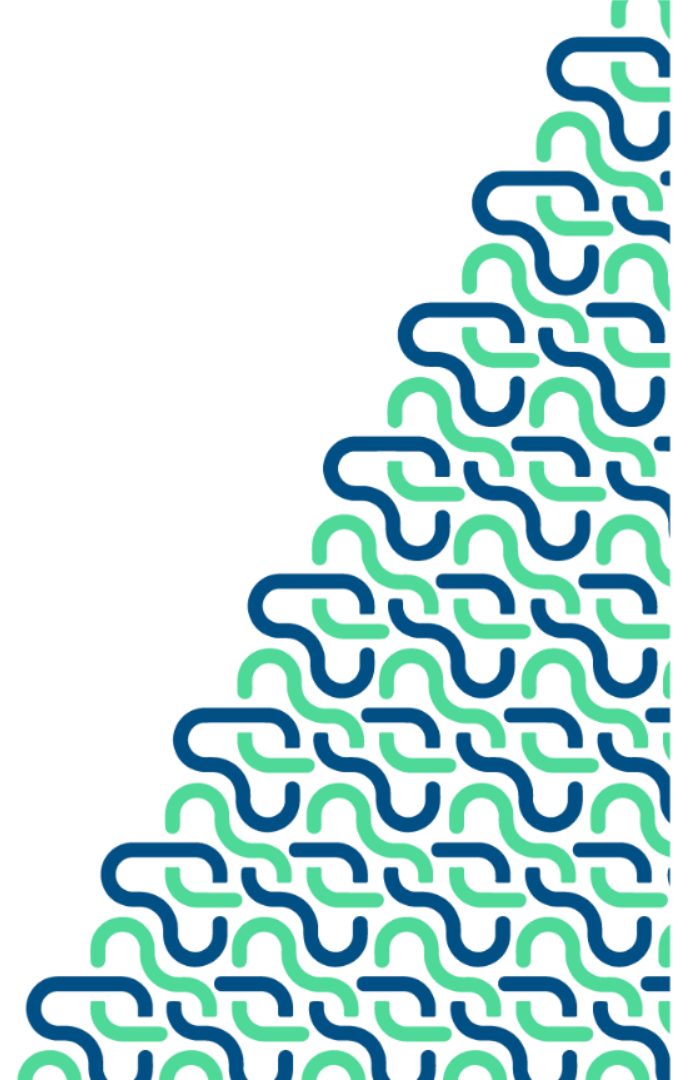# Isabelle Zablit-Schmitz

Europe & International Director, French Ministry of Health & Prevention, Digital Health Delegation

![XpanDH — Expanding Digital Health through a pan-European EHRxF-based Ecosystem]

# European Health Data Space (EHDS)

What it means for Member States

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**The draft EHDS regulation aims to create the FIRST sectoral data space to meet business challenges and sovereignty objectives**

**In a nutshell,**

**Regulating data sharing for healthcare in EU and extending to third countries**
- Individual rights to access their data and better quality of care
- Cross-border exchange infrastructure MyHealth@UE, 30+ countries including third countries
- Prioritized health data

**Single market for digital health data**
- All digital software, applications and MDs in scope
- Common interoperability/security criteria at European level
- Road to convergence of market access harmonization

**Regulating data sharing for re-use of data for public policy, research and innovation**
- Anonymised, pseudonymised and genetic/genomic data
- Authorised/prohibited purposes
- Secure processing environment
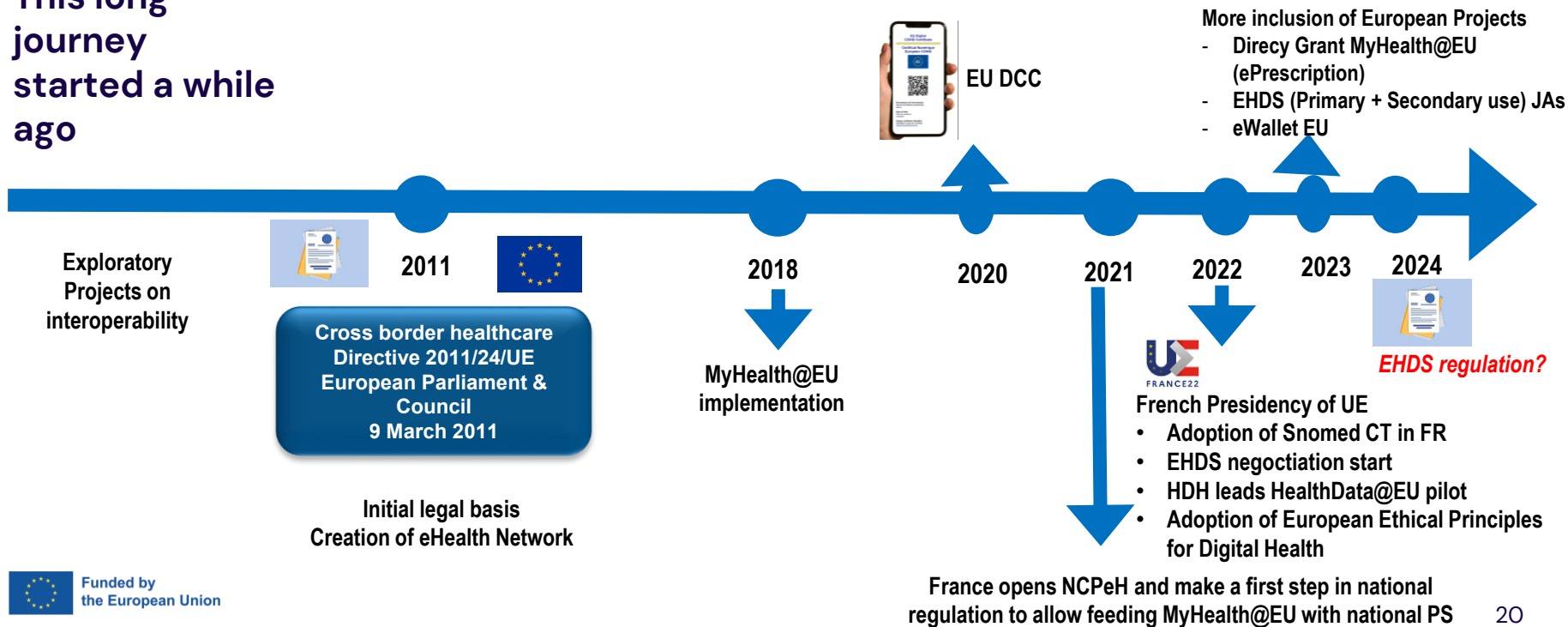- Unique request for European reach

**Strenghtened governance for digital health within the EU**
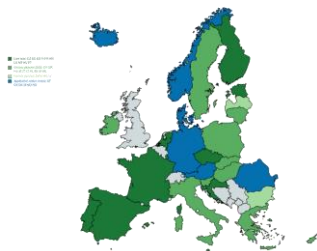
Funded by
the European Union

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**This long journey started a while ago**

**Exploratory Projects on interoperability**

**2011**

**More inclusion of European Projects**
- Direcy Grant MyHealth@EU (ePrescription)
- EHDS (Primary + Secondary use) JAs
- eWallet EU

EU DCC

**Cross border healthcare Directive 2011/24/UE European Parliament & Council 9 March 2011**

**2018**

**2020**

**2021**

**2022**

**2023**

**2024**

*EHDS regulation?*

**Initial legal basis Creation of eHealth Network**

**MyHealth@EU implementation**

FRANCE22

**French Presidency of UE**
- **Adoption of Snomed CT in FR**
- **EHDS negocitation start**
- **HDH leads HealthData@EU pilot**
- **Adoption of European Ethical Principles for Digital Health**

**France opens NCPeH and make a first step in national regulation to allow feeding MyHealth@EU with national PS**

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**SUB GROUP Semantics**
Co-chair Stephanie Weber,
Bfarm Germany



**SUB GROUP Technical IOP**
Co-chair Panayotis Savva,
National eHealth Authority
Cyprus

**Proposed guidelines for use cases and standards**

**eHealth network**



*+ other initiatives as Joint Actions*

**2 standards for MyHealth@EU**

HL7® FHIR®    SNOMED CT
The global language of healthcare

**Guidelines by use case**
- Patient Summary (to IPS)
- ePrescription
- Lab Results

**In process**
- Imaging report & images
- Hospital discharge letter

**More to come**
- Original Clinical Documents
- Rare diseases part of IPS
- Vaccination card

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# The risks for Europe without a European Health Data Space approved sooner rather than later?



**Current Member States planning of implementation**

| | Wave 1<br>2018-2019 | Wave 2<br>2019-2020 | Wave 3<br>2020-2021 | Wave 4<br>2021-2022 | Wave 5<br>2022-2023 | Wave 6<br>2023-2024 | Wave 7<br>2024-2025 | Wave 8<br>2025-2026 |
|---|---|---|---|---|---|---|---|---|
| **Patient Summary** | CZ, HR, LU, MT, PT | | FR | NL, ES | CY, EE, EL, FI, HU, IE, IT | BG, LT, LV, SI | DE, DK, IS, NO, SK | |
| **ePrescription et eDispensation** | EE, FI, HR, PT | | | ES, PL | CY, CZ, HU, EL, IE, IT, LT, SE | BG, LU, LV, SI | AT, DK, NO, RO | |

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**Transition efforts will be huge for all, and worth the journey**



**Citizens**



**Health professionals**

**New rights and New Services have no value if not driven by USAGE – this is our key challenge**
- Communication
- Training
- Acculturation
- Changes in ways of working

# The risks for Europe without a European Health Data Space approved sooner rather than later?



**Transition efforts will be huge for all, and worth the journey**

**European requirements**

**National requirements**

**Software providers**

**New roles and responsibilities split and coordination between European and National levels, requiring ANTICIPATION and foreseen synchronization – this is our key challenge**

- Communication
- Training
- Changes in ways of working for standard adoption
- Collaborative processes and transparency

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**How does it work in France ?**

**National requirements**

**Software providers**

**Health information systems interoperability framework (CI-SIS)**

The Health Information Systems Interoperability Framework (CI-SIS) sets out
- rules for communicating health information systems in the health, medico-social and social sectors. T

**The development of a transparent and secure digital health system requires compliance with reference frameworks in order to** :
- Create the conditions for the development and regulation of digital healthcare
- Enable professionals and users to benefit from digital innovation and change
- Assist public authorities in managing digital projects of national interest

# The risks for Europe without a European Health Data Space approved sooner rather than later?

## How does it work in France ?

*The health information systems interoperability framework (CI-SIS) for exchanging and sharing health data*
Avoid developing a specific interface for each IS with which it communicates, thereby reducing the cost of integrating new interfaces and the technical issues of interoperability when choosing products, so that the focus can be on business functionality, facilitating the use of products from international publishers in the French context, and enabling value-added uses of the data processed without the need for human reprocessing.

The CI-SIS is based on mature and stable international norms and standards, and **is being developed in consultation with representatives of healthcare and medico-social professionals and health information system publishers**. –

The CI-SIS consists of syntactic (data structuring and format) and semantic (value sets and reference terminologies) specification components.
**These components are organised into three layers:**
-   Business Layer, whose components specify exchangeable business content;
-   Service Layer, whose components specify the functionalities implemented and the data exchanges enabling them to be activated;
-   Transport Layer, whose components specify the transport of information.

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**Transition efforts will be huge for all, and worth the journey**

**EHDS regulation**



**Adaptation of national authorities**

**National requirements**

**New roles and responsibilities create new environment for authorities**
- New roles, and sometimes bodies
- Changes in ways of working with new processes

# The risks for Europe without a European Health Data Space approved sooner rather than later?

**What if everything goes well ?**

**If not, how to mitigate ?**



**Citizens**

**Software providers**

**Health professionals**

They all should have incentives to push for **further harmonization and convergence**

Experience and reality demonstrate **it is about vision, time and money**

**Therefore progress with actionable concrete steps and successes will be a must**

# Questions & Answers

# Thank you for joining!

@xpandh_project