EHTEL

Collaborating for Digital Health and Care in Europe

CELEBRATING 25th ANNIVERSARY

European Health Data Space (EHDS) Implementers Task Force Kick-off Online Meeting

5 November 2024, 14:30 - 16:00 CET

5 November 2024

Practicalities

- *The webinar will be recorded*
- *Slides and recording will be shared (in pdf) within the EHTEL community*
- *To help ensure a successful webinar please:*
  - Stay muted
  - Use reactions/emojis during the presentations
  - Use the chat to make comments or raise your questions
  - Raise your hand if you'd like to speak
  - If you speak, turn on your video and say who you are

European Health Data Space (EHDS) Implementers Task Force Kick-off Online Meeting: Agenda

- ***Introduction***
  Marc Lange, EHTEL
- ***EHDS Regulation in relation to primary use: data use, governance, landscape***
  Ander Elustondo Jauregui, DG Santé

---------- Q&A ----------

Round Table on the implementation challenges

- Michael Johansen, MedCom (DK)
- Klára Jiráková, Ministry of Health (CZ)
- Brikena Kolaj, Engineering Informatica
- Sabato Mellone, University of Bologna
- Shane Fitch, Lovexair Foundation
- Moderator: Michael Strübin, EHTEL

---------- Q&A ----------

- ***Next steps***

European Health Data Space (EHDS) Implementers Task Force

- ***An EHTEL multi-stakeholder Task Force:***
  - "Task Forces are task-based groups of EHTEL members (and may also include non- EHTEL members) that develop and deliver responses on behalf of EHTEL to key issues or themes […]"
  - It will be a mix of on-line and in person meetings, in Brussels or elsewhere, if hosted by an EHTEL member, over 2025 and 2026.
- ***Two workstreams foreseen***
  1. What needs to be done practically with EHR systems to prepare EHDS implementation?
  2. What are the main challenges in relation to individuals' rights to electronically access and download their health data?
- ***Expected outcomes***
  - Learning from each other – and reflecting together – on the EHDS implementation challenges.
  - Publishing conversation summaries and briefing notes, and engaging with the European Commission, the EHDS Board, the Stakeholder Advisory Board and EHDS-related projects like xShare, Xt-EHR, i2X and MyHealth@MyHands.

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- ***Next steps***

State of play and implementation of the EHDS

EHTEL's EHDS Implementers' Task Force
November 2024

Ander Elustondo Jauregui
Team Lead/Coordinator
DG SANTE, C1

Agenda

1. Introduction to the EHDS Regulation: A closer look on primary uses and certification of EHR systems
2. Implementation of the EHDS: Project landscape
3. Governance of the EHDS
4. Q&A

Introduction to the EHDS Regulation

A closer look on primary uses and governance

European Commission

Reminder on the timeline for the EHDS regulation

Previous steps

- **Provisional agreement** reached during the fifth trilogue 14/03/2024.
- Examination of the compromise by MS in COREPER on 22/03/2024
- Vote in EP ENVI-LIBE joint committee meeting 09/04/2024
- Vote in plenary session in EP **24/04/2024**

Is it done? Almost…

- Corrigendum procedure **ongoing**
- Expected final adoption in EP (expected year-end): Corrigendum procedure, as a package.
- Corrected text to be published in Official Journal of the EU (OJ), expected: **early 2025.**
- **Entry into force:** 20 days after the publication on the OJ

EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems

Benefits for patients and health professionals

For patients

- Immediate and free of charge access to their own electronic health data in the priority categories.
- Easy sharing of data with health professionals, including cross-border.
- Possibility to add data, restrict access, see who accessed data, ask for rectification of errors.
- Have access in the European electronic health record exchange format, improving interoperability.
- Easy to use mechanisms for delegated access and appointing proxies
- (dependent on Member State choice): possibility for a full opt-out from exchanges using EHDS infrastructures for primary use.

For health professionals

- Easier and quicker access to their patients' data, including cross-border.
- European electronic health record exchange format will facilitate data sharing across systems by increasing interoperability.

Priority categories

Group 1 (“basic”)

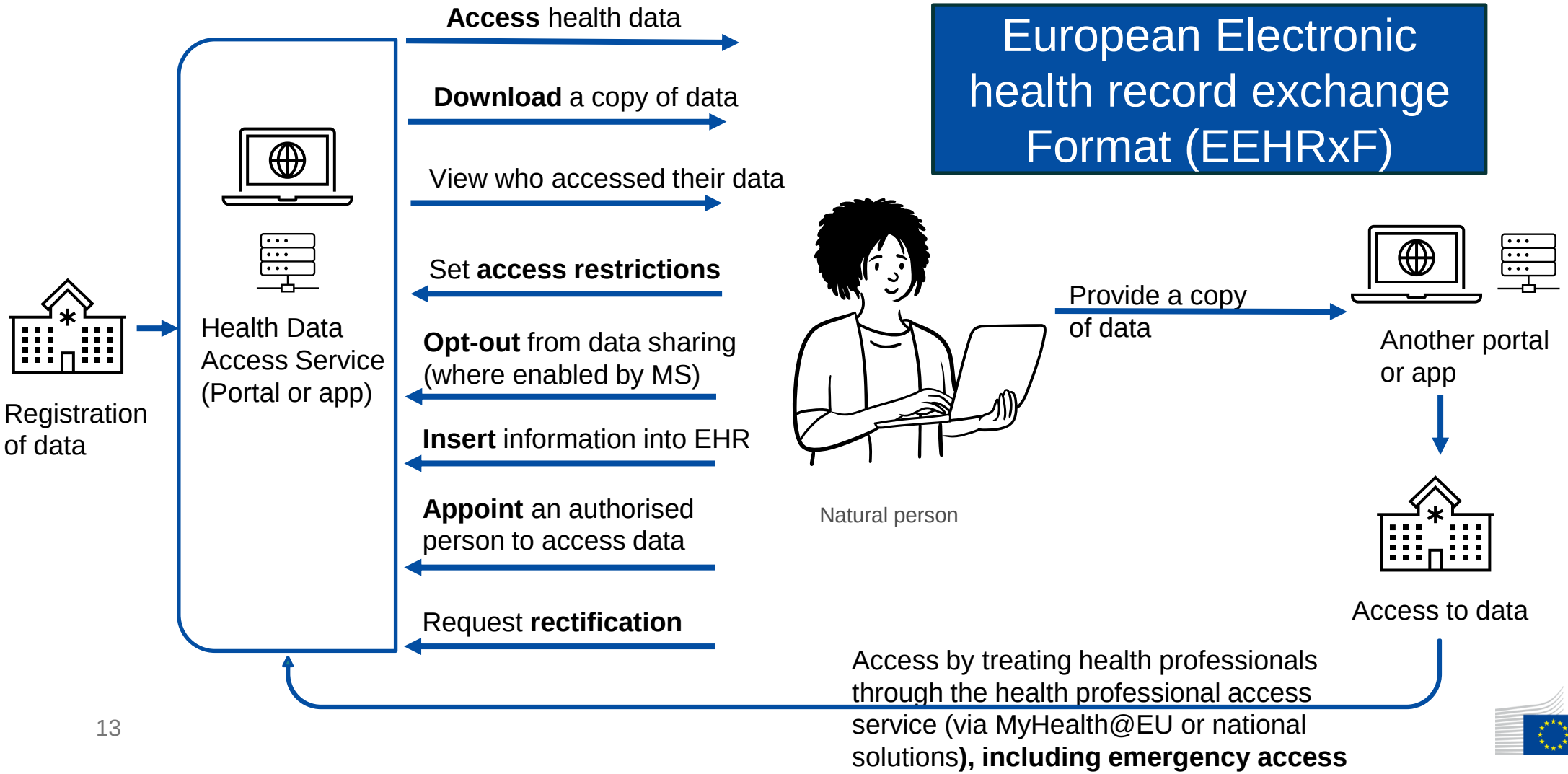
- Patient summaries
- Electronic prescriptions
- Electronic dispensations

Group 2 (“advanced”)

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

European Electronic health record exchange Format (EEHRxF)

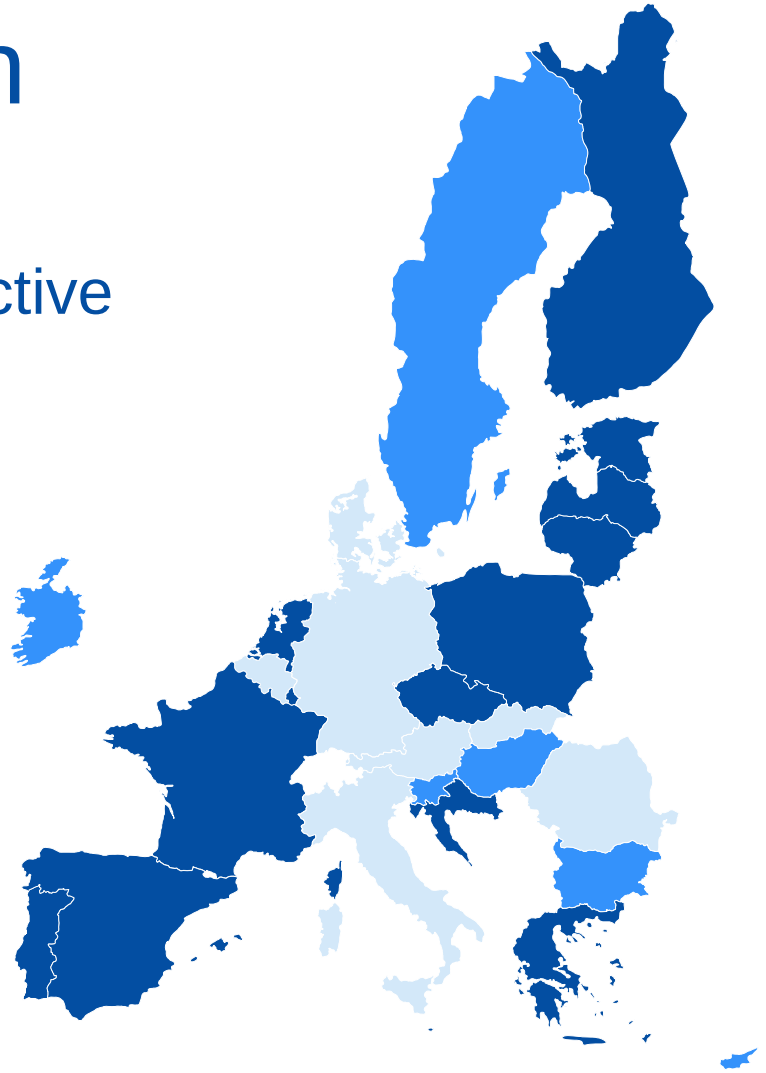
Rights of natural persons in primary use



Building on existing cooperation

MyHealth@EU under Cross-border Healthcare Directive

- Voluntary system for exchanging patient summaries, prescriptions and dispensations (≈ first group of priority categories)
- **14 MS** live with at least one service



Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories

Benefits of requirements on EHR systems

For manufacturers

- Easier market access across Member States due to harmonised requirements for interoperability and logging components.
- Increased interoperability reduces switching costs, making market entry easier.

For patients

- Increased interoperability facilitates data sharing, saving time and money.

For healthcare providers

- Can be assured that any EHR system they buy enables them to comply with interoperability requirements.
- Increased interoperability:
  - saves time and money by not uselessly repeating tests;
  - reduces switching costs, decreasing vendor lock-in effects.

Scope of harmonisation

EHR systems must contain **two harmonised components**, starting 2028/2030 depending on which kind of data they process:

Interoperability component

- Provides capability to import/ export data in EEHRxF

Logging component

- Provides capability to generate the logs of access

Member States remain free to have requirements on other parts of EHR systems, provided they do not interfere with the harmonised components

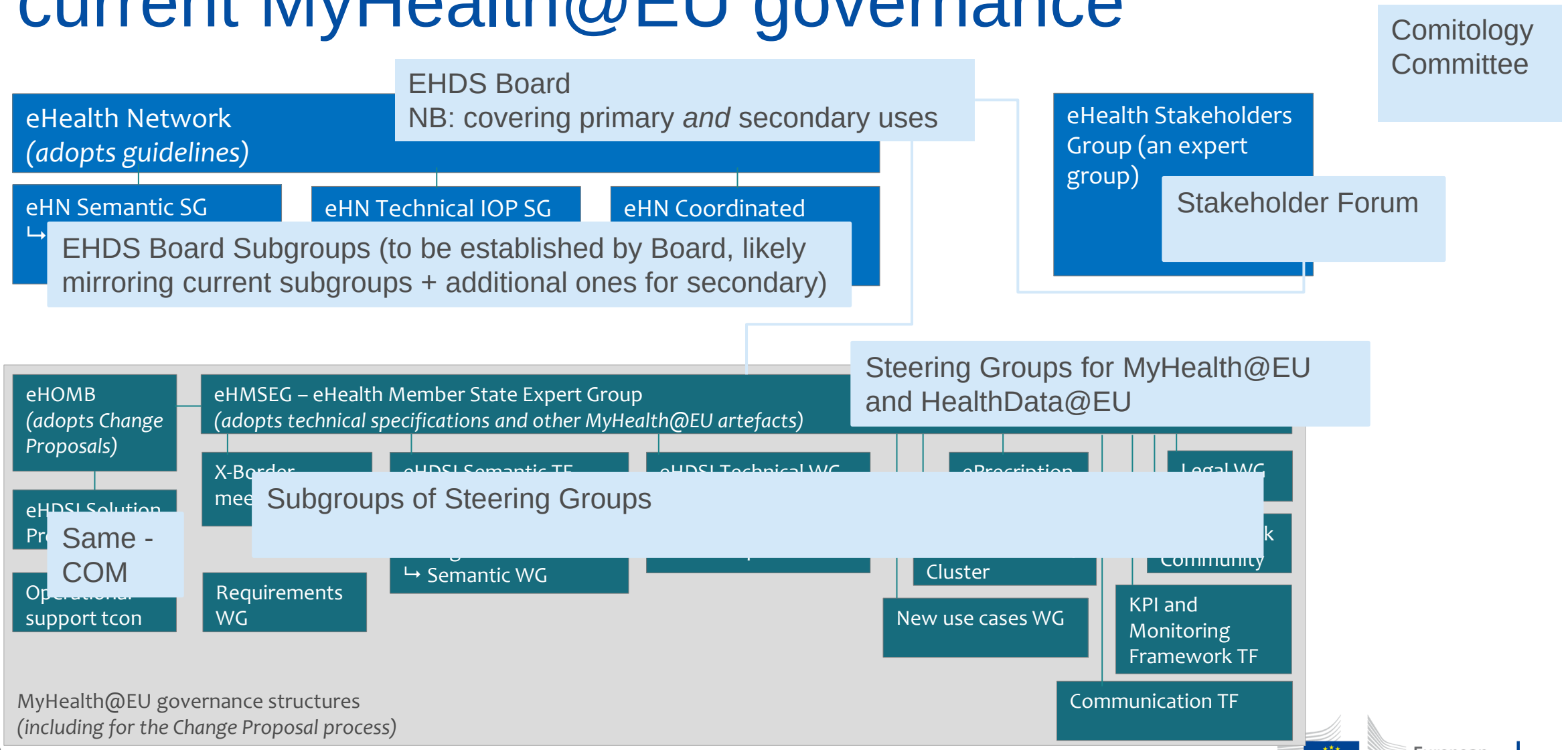
Certification

- **Self-declaration of conformity**
- **Digital testing environments** across Member States for ex-ante assessment of compliance with the requirements
  - To assess compliance of harmonised components with essential requirements
- **Registration of certified EHR systems** in an EU database
  - For transparency and accountability on certified EHR systems

Governance of the EHDS

European Commission

Comparison to eHealth Network, subgroups, current MyHealth@EU governance



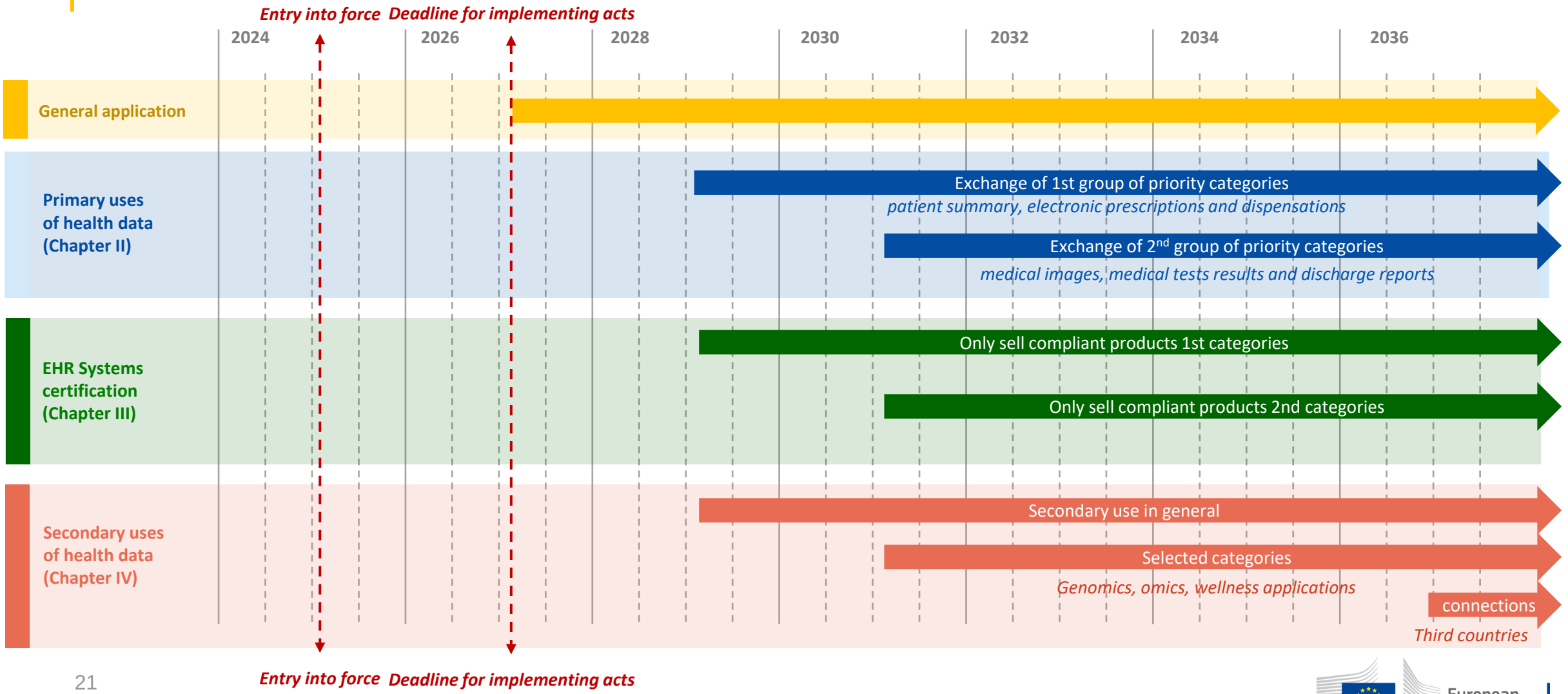
Implementation of the EHDS

Project landscape

European Commission

Implementation of the EHDS Regulation

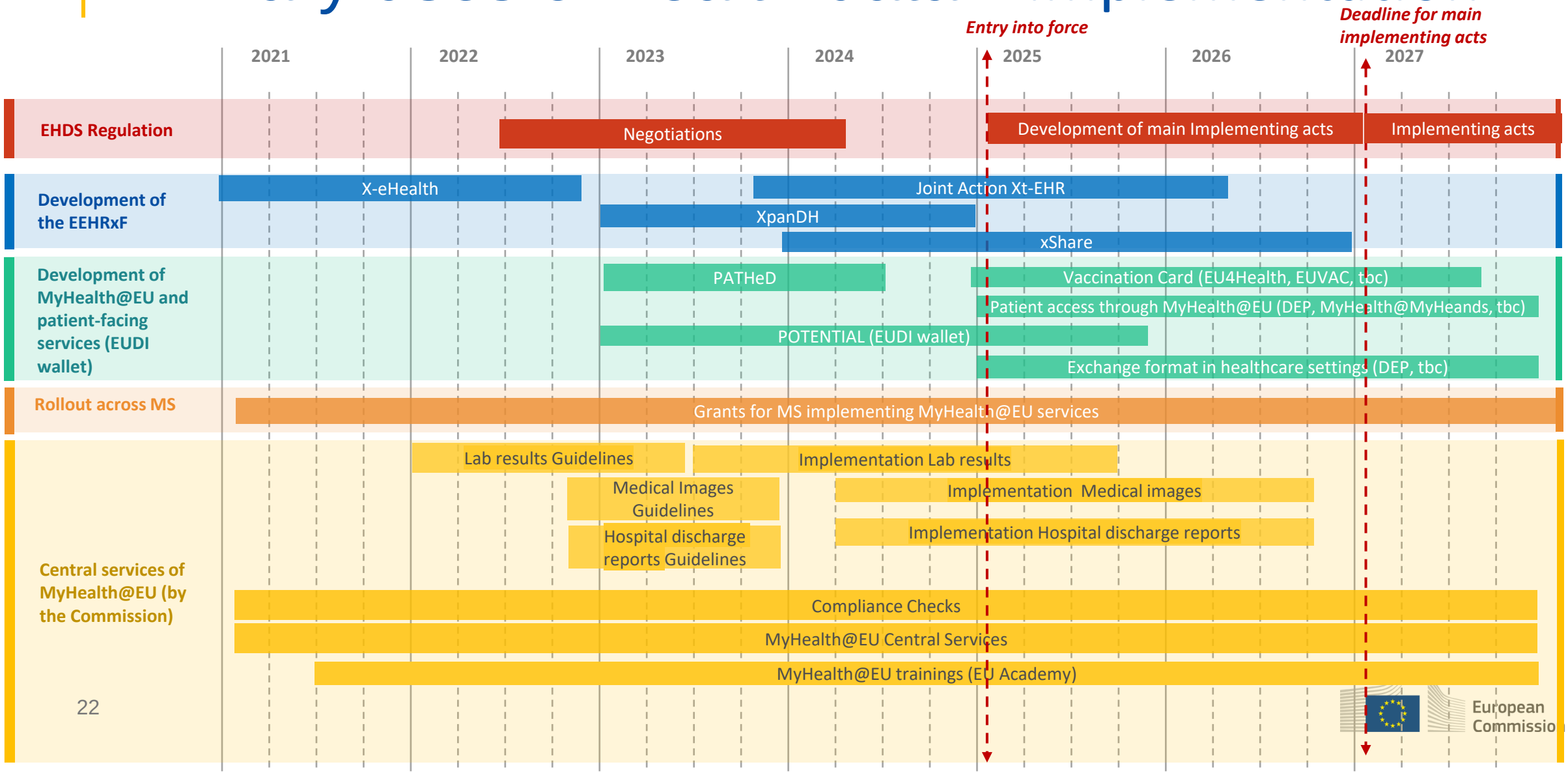
Timelines are indicative.



European Commission

Timelines are indicative.

Primary uses of health data – Implementation



European Commissio

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

xShare

- Practical implementation of patient-mediated workflow for data portability
- Further development of the exchange format (e.g. care plans, telemonitoring)

Further actions

- In-service deployment of the EEHRxF
- Patient access to health data using MyHealth@EU
- EEHRxF support centre
- EUVAC

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

Joint action Xt-EHR

- 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 ePrescriptions/ eDispensations**
- **Original Clinical Documents**
- **Lab results, hospital discharge reports, medical imaging**
- **Further data categories**

Thank you

State of play and implementation of the EHDS

EHTEL's EHDS Implementers' Task Force
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medcom

- Michael Johansen
- Chief Consultant

mjo@medcom.dk

https://www.linkedin.com/in/michael-johansen-6799648/

Has developed standards for sematic interoperability in MedCom for 10 years, and has developed the Danish assessment scheme, for messaging, document sharing and majority of data services.
Besides development MedCom performs the test and certification for conformance with the standards and compliance with the requirements.

Attached the xShare project, co-led by MedCom and HL7 Europe
- Participated in several international projects (ex. EURO-CAS)

Member of the XpanDH project advisory board

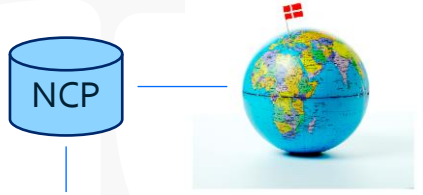
Member of the approval board at Danish Standards (mirror committee S-273)
- CEN TC251 WG1 and WG2
- ISO TC215 WG1, WG2 and WG3

Member of HL7 Denmark and HL7 International

Member of the Danish project coordinating EHDS network

Legacy

- Existing national Infrastructure
  - Allowed to use data from existing national repositories instead from EHR systems?
  - Support for both existing national upload formats + new EEHRxF format in EHR systems?



National Service Platform – Documents | Appointment | Pregnancy | Telehealth | Careplan

Services | Medication | Lab.order | Lab.report | Referral | Immunization | Intolerance

Messaging (VANS) – transition to eDelivery | Message

Semantic Interoperability

- Mapping terminology
  - Conflicts between national stored legacy data and EEHRxF format and content?
- Automation based upon structured data
  - Ambition for more than share PDF reading (reduce clinicians burden, documentation and reuse/summary)
- Conformance assessment scheme
  - Vendors self-assessment combined with existing national certification scheme
  - Portability cross-border of certificate/approval?

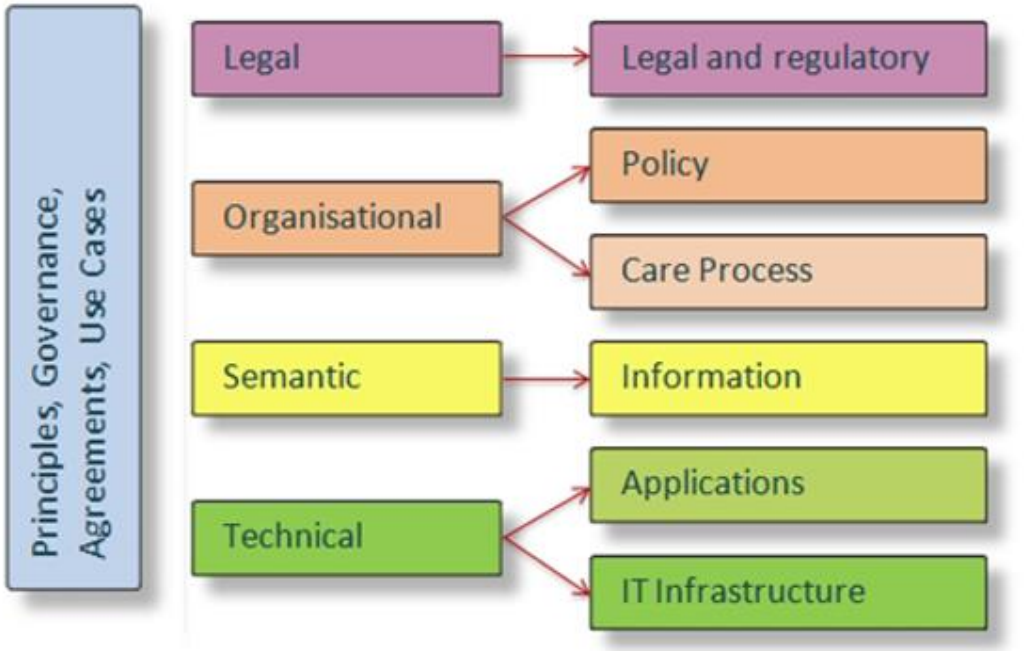


Figure 1: Refined eHealth European Interoperability Framework

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EHDS Implementation Challenges from Member State point of view

Klara Jirakova

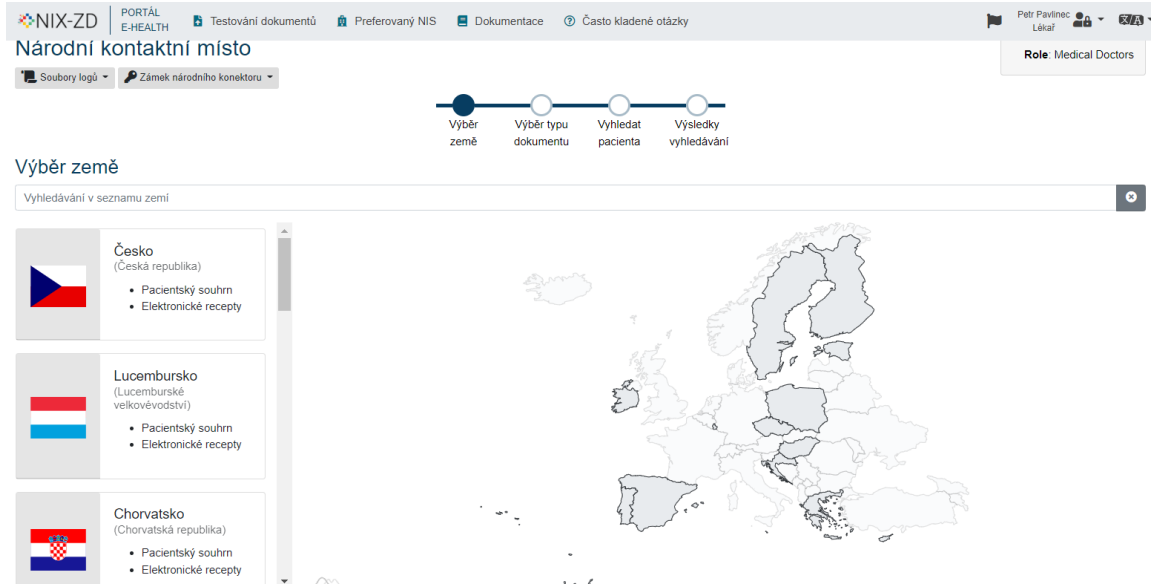
Czech Republic – Ministry of Health

National Contact Point for eHealth

EU Level – MyHealth@EU and CZ

- CZ National Contact Point for eHealth established and operational
  - Patient Summary service – with 8 EU MS (HR, LU, FR, PT, NL, ES, MT, EE)
  - ePrescription/eDispensation service – with 8 EU MS (PL, HR, ES, EE, LV, PT, FI, EL)

4.11.2024 12:35:23	4.11.2024 12:35:25	1 686 ms	INBOUND	ITI-55	PATIENT_IDENTIFICATION_RESPONSE	PL	CZ
4.11.2024 12:20:57	4.11.2024 12:21:02	5 454 ms	OUTBOUND	ITI-55	PATIENT_IDENTIFICATION_QUERY	CZ	PL
4.11.2024 11:45:41	4.11.2024 11:45:42	550 ms	INBOUND	ITI-41	DOCUMENT_EXCHANGED_RESPONSE	HR	CZ
4.11.2024 11:43:36	4.11.2024 11:43:36	505 ms	INBOUND	ITI-39	DOCUMENT_EXCHANGED_RESPONSE	HR	CZ
4.11.2024 11:43:28	4.11.2024 11:43:28	493 ms	INBOUND	ITI-38	DOCUMENT_LIST_RESPONSE	HR	CZ
4.11.2024 11:42:48	4.11.2024 11:42:49	537 ms	INBOUND	ITI-55	PATIENT_IDENTIFICATION_RESPONSE	HR	CZ
4.11.2024 10:41:28	4.11.2024 10:41:29	633 ms	INBOUND	ITI-38	DOCUMENT_LIST_RESPONSE	ES	CZ
4.11.2024 10:41:18	4.11.2024 10:41:18	414 ms	INBOUND	ITI-55	PATIENT_IDENTIFICATION_RESPONSE	ES	CZ
4.11.2024 10:36:38	4.11.2024 10:36:38	406 ms	INBOUND	ITI-38	DOCUMENT_LIST_RESPONSE	ES	CZ
4.11.2024 10:36:33	4.11.2024 10:36:34	1 319 ms	INBOUND	ITI-41	DOCUMENT_EXCHANGED_RESPONSE	ES	CZ
4.11.2024 10:35:45	4.11.2024 10:35:45	717 ms	INBOUND	ITI-41	DOCUMENT_EXCHANGED_RESPONSE	PL	CZ



CZ – National level state of play

☹

- Decentralized healthcare = no central source of data for priority categories, except ePrescription/eDispensation and vaccinations.
- Patient data stored in healthcare provider information systems.
- Patient documentation now mostly unstructured, uncoded, exchanged only partially.
- Only 14 hospitals (5 EHR vendors) now able to provide partially coded PS – HL7 CDA
- The knowledge/usage of standards is low, lack of semantic and interoperability experts.

☺

- Resources - CZ is using RRF funds for strengthening central services (patient registries, national testing framework, term. Server, display tool, mobile app….), EU structural funds (ERDF) for improving IS on healthcare level (hospitals).
- Construction of new network of regional affinity domains (repository and communication platforms) based on IHE profiles including FHIR family
- New national EHR standards are designed to be fully compatible with EHDS and future implementation acts (Xt-EHR project).
- 6 years of experience with NCPeH operation and solving interoperability challenge.

Thank you!

Klara Jirakova
Czech Republic – Ministry of Health
National Contact Point for eHealth

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Healthcare

Brikena Kolaj
Product Owner Lead

https://www.linkedin.com/in/brikenakolaj/

WATCH VIDEO | READ WHITEPAPER

At a Glance

Healthcare

We are transforming healthcare through a total digitalization of processes and leveraging innovative technologies to safely improve patient care, the quality of work of medical operators and the overall sustainability of the healthcare system.

900+ Professionals

180+ Clients

€170m+ Revenues FY2023

25+ Years of experience

10+ Research projects

55m Bookings managed

1,2m Admissions managed

4,5m Emergency accesses

57m Laboratory tests

ADVISORY

TECHNOLOGY & IMPLEMENTATION

PROPRIETARY SOLUTIONS

MANAGED SERVICES

Our Proprietary Solutions

ellipse
E-Health Clinical ecosystem platform for clinical and care dimensions

DE4Bios
Cloud Biosurveillance Platform

AREAS
E-Health Integrated Platform

Real Time
Governance
Prevention
Privacy
Patient Journey
CURE
Telehealth
EMS
LABORATORY
HR
Taking Care
Accounting
Patient Relationship
CARE
Health
CO-DESIGN
BOOKING
EMR
Pathway & Care Continuity
COLLABORATION
VBHC
Clinical Decision Support System

DISCOVER MORE

EHDS Implementation Challenges

- **Data Interoperability**
- **Privacy and Security Concerns**
- **Data Quality and Consistency**
- **Technical Infrastructure Disparities**
- **Change Management and Training**
- **Legal and Regulatory Complexity**
- **Cost of Implementation**
- **Patient and Stakeholder Engagement**
- **Maintaining Data Accuracy and Real-Time Access**
- **Integration with Existing Systems**

- Overcoming these challenges requires a coordinated approach across EU member states, support for lower-resourced systems, and close collaboration among healthcare providers, policymakers, and technology providers.

EHDS Implementation Challenges

- Data Interoperability: Healthcare systems across the EU vary in data formats, standards, and platforms, making interoperability a complex hurdle. Implementing consistent standards across these systems to allow seamless data exchange will require significant coordination and infrastructure changes.
- **Privacy and Security Concerns**: Healthcare data is highly sensitive, and any breaches can have serious implications. Ensuring robust security measures that align with GDPR and other local data protection laws will be essential but challenging, especially with cross-border data exchanges.
- **Data Quality and Consistency**: For predictive and analytical models to work effectively, data quality is crucial. Inconsistent or incomplete data from different healthcare providers can lead to inaccurate insights and affect patient care, creating a need for rigorous data quality standards.
- **Technical Infrastructure Disparities**: EU member states have differing levels of healthcare IT infrastructure. Less developed systems may struggle with the investment and technology needed to implement EHDS, creating disparities in access and data availability across countries.
- **Change Management and Training**: Introducing EHDS involves changes in workflows, data management practices, and technology use, requiring extensive training for healthcare professionals. Resistance to change or lack of familiarity with new systems can slow down adoption and reduce efficiency.

EHDS Implementation Challenges

- **Legal and Regulatory Complexity**: Each country has its own legal and regulatory framework and aligning them with the EHDS regulation could take time and require legislative adjustments. Ensuring compliance while respecting national regulations will be a key challenge.
- **Cost of Implementation:** Upgrading systems, enhancing security, and training staff require significant financial resources. Not all healthcare systems may have the budget for these investments, and support may be needed to avoid financial disparities.
- **Patient and Stakeholder Engagement**: Effective implementation relies on trust and willingness from patients to share their health data. Building this trust, educating patients on data use, and addressing concerns about privacy will be vital for EHDS's success.
- **Maintaining Data Accuracy and Real-Time Access**: Ensuring that patient data is both accurate and updated in real-time across various systems and borders is complex but necessary for effective patient care and predictive analytics.
- **Integration with Existing Systems**: Many healthcare systems use legacy software that may not be compatible with EHDS standards. Integrating or upgrading these systems without disrupting current operations will be challenging.

Healthcare

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Sabato Mellone, PhD in Biomedical Engineering
sabato.mellone@unibo.it
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My main research activities are in the area of data and signal processing, **medical informatics**, medical devices, ICT in clinical practice, wearable and embedded sensors, personal health systems design and validation, eHealth and mHealth applications.

- Co-founder of mHealth Technologies s.r.l., spin-off company of the University of Bologna **manufacturing medical devices**.
- Responsible for the technology development and **health data management in clinical trials** within multidisciplinary EU projects.
- Partner in the Second Joint Action Towards the European Health Data Space – **TEHDAS2**:
- CTO of the **AlmaHealthDB** infrastructure in Bologna (https://www.almahealthdb.it/)
- CTO of spoke 1 within the DARE (DigitAl lifelong pRevEntion) initiative funded by the Italian Ministry for University & Research focusing on **digital prevention**
- Member of **HL7** Italia

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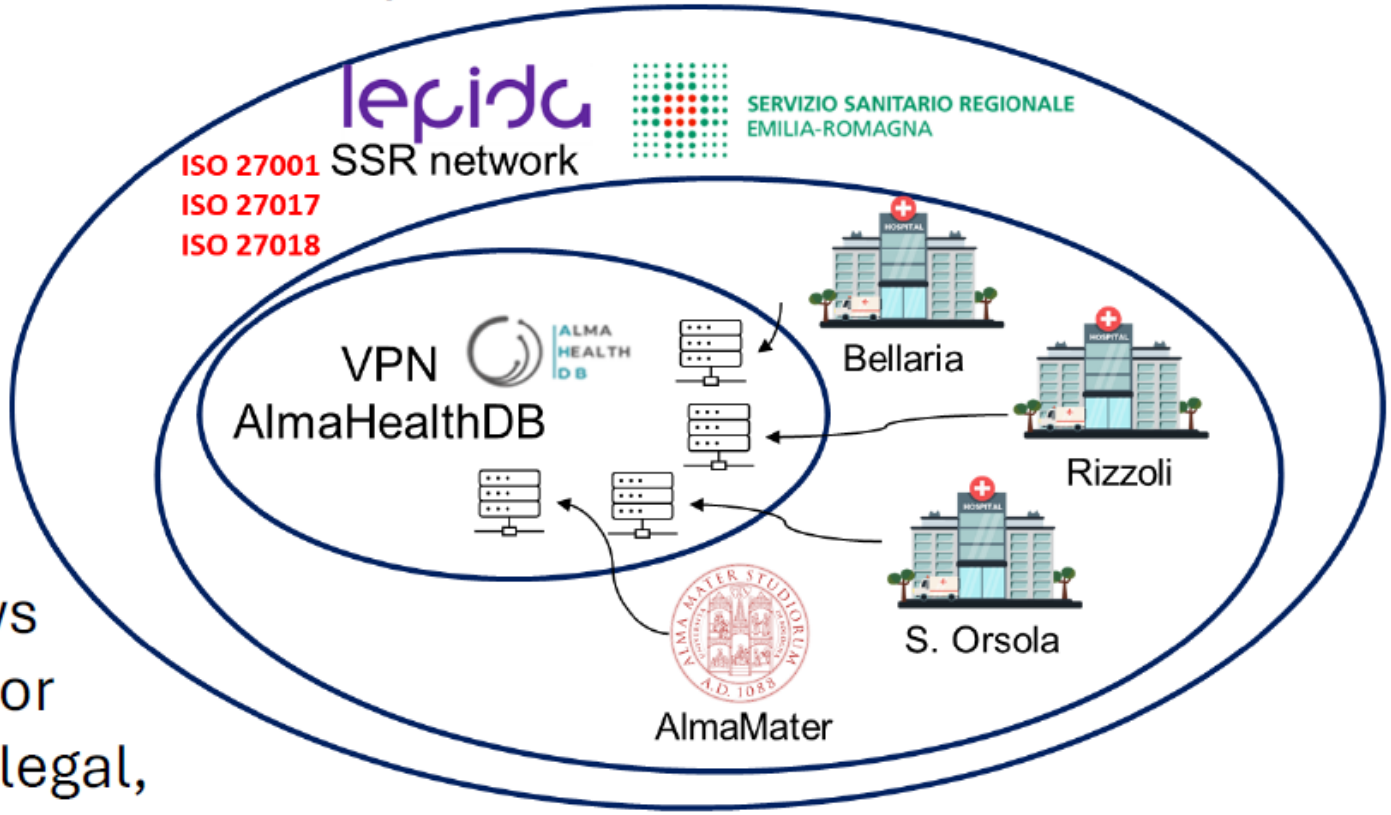
ALMA HEALTH DB

DARE
DIGITAL LIFELONG PREVENTION

AlmaHealthDB

The AlmaHealthDB infrastructure is funded and shared by the **University of Bologna** and the three research hospitals in Bologna:

- **Rizzoli Orthopaedic Institute**
- **Institute of Neurological Sciences**
- **S. Orsola-Malpighi Polyclinic**



The AlmaHealthDB infrastructure allows collecting and processing health data for research purposes in compliance with legal, organizational, and regulatory requirements.

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ALMA HEALTH DB

DARE
DIGITAL LIFELONG PREVENTION

The perspective of Healthcare Institutions (Data Holders, in the EHDS regulation)

- We are working on the technological, organizational, and regulatory alignment of our infrastructure, and related processes within research hospitals, with the vision of the EHDS and we are experiencing firsthand the challenges and concerns that healthcare institutions are facing.
- This is especially relevant as a process similar to what is envisioned with the EHDS has already begun in Italy, thanks to funding from Next Generation Europe, with the definition of the so-called Ecosistema dei Dati Sanitari (Health Data Ecosystem).

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ALMA HEALTH DB

DARE
DIGITAL LIFE-LONG PREVENTION

The perspective of Healthcare Institutions (Data Holders, in the EHDS regulation)

- A fundamental aspect of the entire process concerns data curation and standardization, which are crucial as they can potentially become bottlenecks.
- While in many cases automation is feasible—for example, the electronic health record software provider can export structured data directly in the format required by the EHDS—at the outset and in other parts of the process, it is inevitable that operators will need to perform manual data entry, select appropriate ontologies, labels, etc.
- This process is time-consuming even when it becomes routine and requires specific skills that the typical operator may lack.

The perspective of Healthcare Institutions (Data Holders, in the EHDS regulation)

- It would be conceivable to have dedicated staff for this purpose, but this would require additional resources, and it is unclear if, when, and under what conditions they would be provided.
- Linked to the topic of resources, both human and financial, there is also the issue of updating local infrastructures, which must be capable of handling functions and data types that are currently not present.
- This, too, would require investment in personnel and IT tools.

The perspective of Healthcare Institutions (Data Holders, in the EHDS regulation)

- All of these processes are additional burdens, and healthcare is already under significant strain due to staffing shortages and high costs.
- It is unrealistic to expect this entire process to be sustainable without local investments.

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Lovexair

Together : people & professionals we work to create experiences to enrich our opportunities to improve health and equitative access to care for all

Lovexair Happair

Collaborating for Digital Health and Care in Europe EHTEL

Digital Health Uptake

Shane Fitch CEO & Founder Lovexair Foundation

Member B3 Integrated Care EU-Established HappyAir 2011 Digital Health Ecosystem

26 years experience international patient advocacy and leadership son born with rare disease Alpha-1

Member Global Patient Advisory Forums with key stakeholders in respiratory and digital health spheres

Co- design & validate hybrid- integrated care models with clinical experts & hospitals

Implement equitative access care programs across Spain-Latam

Have registered consortiums for EU calls with vision for AI & Respiratory Health : Improvid, Improvair…

Advocate for respiratory and humanized data driven solutions, CRConnect and Air Quality working groups ELF/ERS

Key collaboration Breathe Mom film impact on health from climate change & assessment tool

presidencia@lovexair.com

Lovexair Foundation
care for your lungs

Happyair

Patients, civic organizations & institutions should work together for the EHDS. Is there an opportunity for us to join the regulatory supervisory committee in any capacity, to better advocate & represent ethics & governance interests to promote pro-active citizen engagement and support this important initiative with key stakeholders ?

We understand the complexity of undertaking EHDS and adding new systems progressively, as well as meeting deadlines and goals. What is the timeframe expected from organizations to meet this compliance and what penalties likely, if compliance and joining the EHDS are not met fully?

Can we actively participate in EHDS channels, for and on behalf of patients, to meet regulatory compliance ourselves and directly engage with our digital health ecosystems & patient data? How can we achieve this?

Happ air

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European Health Data Space (EHDS) Implementers Task Force
Kick-off Online Meeting
Round Table on the Implementation Challenge: Q&A

- *Michael Johansen, MedCom (DK)*
- *Klára Jiráková, Ministry of Health (CZ)*
- *Brikena Kolaj, Engineering Informatica*
- *Sabato Mellone, University of Bologna*
- *Shane Fitch, Lovexair Foundation*

- *Moderator: Michael Strübin, EHTEL*

European Health Data Space (EHDS) Implementers Task Force Kick-off Online Meeting: Agenda

- ***Introduction***
  Marc Lange, EHTEL
- ***EHDS Regulation in relation to primary use: data use, governance, landscape***
  Ander Elustondo Jauregui, DG Santé

---------- Q&A ----------

Round Table on the implementation challenges

- Michael Johansen, MedCom (DK)
- Klára Jiráková, Ministry of Health (CZ)
- Brikena Kolaj, Engineering Informatica
- Sabato Mellone, University of Bologna
- Shane Fitch, Lovexair Foundation
- Moderator: Michael Strübin, EHTEL

---------- Q&A ----------

- ***Next steps***

European Health Data Space (EHDS) Implementers Task Force Kick-off Online Meeting: Next steps

- *The video, the presentation and the meeting report will be published on the **EHTEL Member workspace***

- *Your feedback on the two workstreams*
  1. What needs to be done practically with EHR systems to prepare EHDS implementation?
  2. What are the main challenges in relation to individuals' rights to electronically access and download their health data?
- *Agenda for the next meetings?*

- *On-line or in person (from lunch to lunch)?*

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Thank you

EHTEL

Collaborating for Digital Health and Care in Europe