Helsedirektoratet

Standardiseringsutvalget for internasjonale e-helsestandarder

Møte 2-24

Skøyen / Teams 13.06.2024

Agenda

Sak	Tid	Tema	Type
6/24	10.00 – 10.30	**Velkommen / Orientering fra Helsedirektoratet** *Georg F. Ranhoff (Helsedirektoratet)*	Orientering
7/24	10.30 – 11.00	**Sertifiseringsordning for EPJ-systemer** *Marianne Bårtvedt van Os (Helsedirektoratet)*	Drøfting
8/24	11.00 – 12.00	**XpanDH goes to Norway** *Henrique Martins (FCS-UBI, ISCTE-IUL)*	Drøfting
	12.00 – 12.45	**Lunsj**	
9/24	12.45 – 13.15	**Plan for internasjonale standarder** *Ingvar Sørlien (Helsedirektoratet)*	Drøfting
10/24	13.15 – 14.00	**Helse-NIM for kritisk info – prosess fremover** *Mari Svardal (Helsedirektoratet)*	Drøfting

Helsedirektoratet

Standardiseringsnyheter fra Helsedirektoratet

Georg F. Ranhoff - Helsedirektoratet

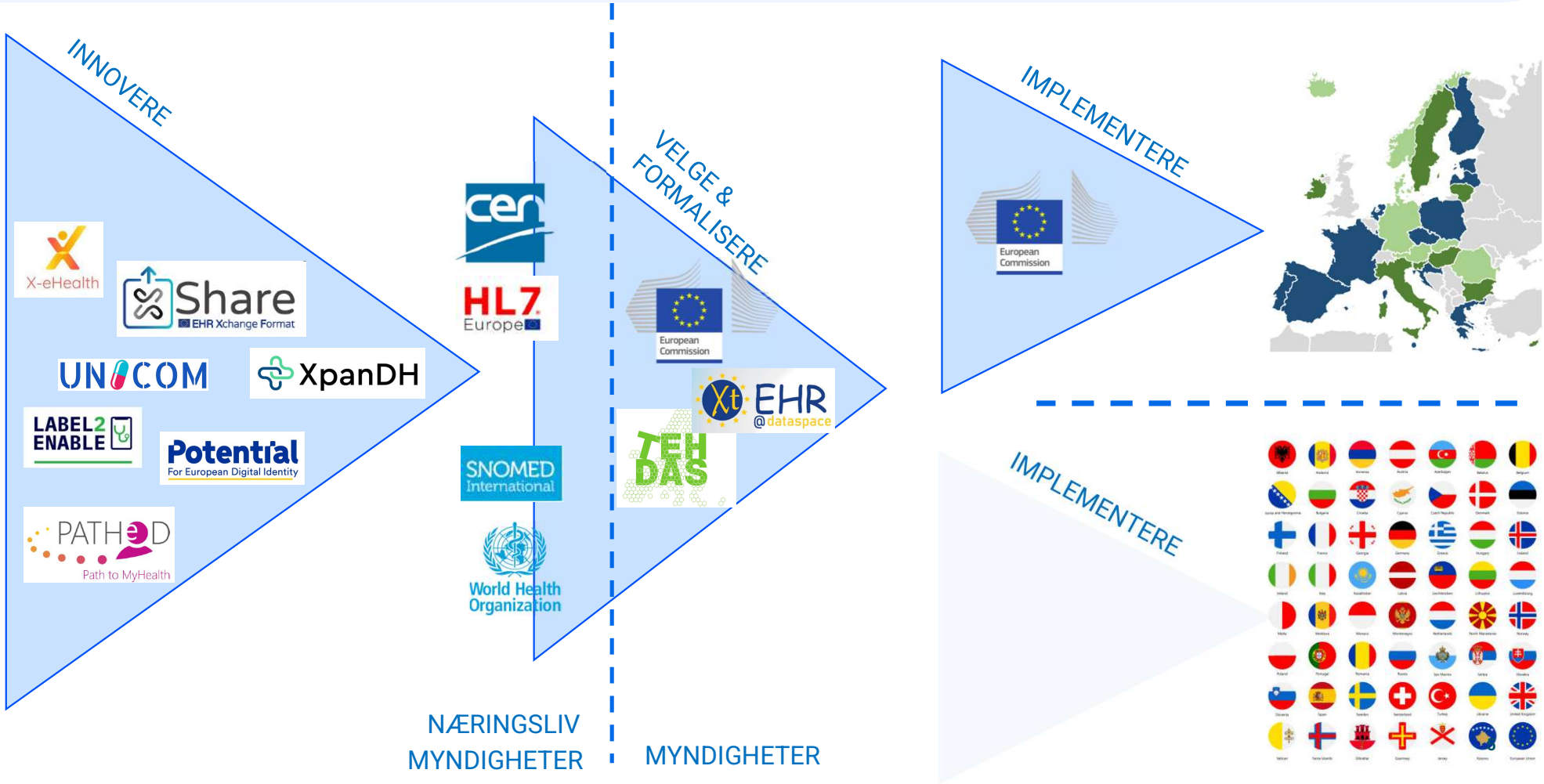
EHDS in a nutshell – what is it about?

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.

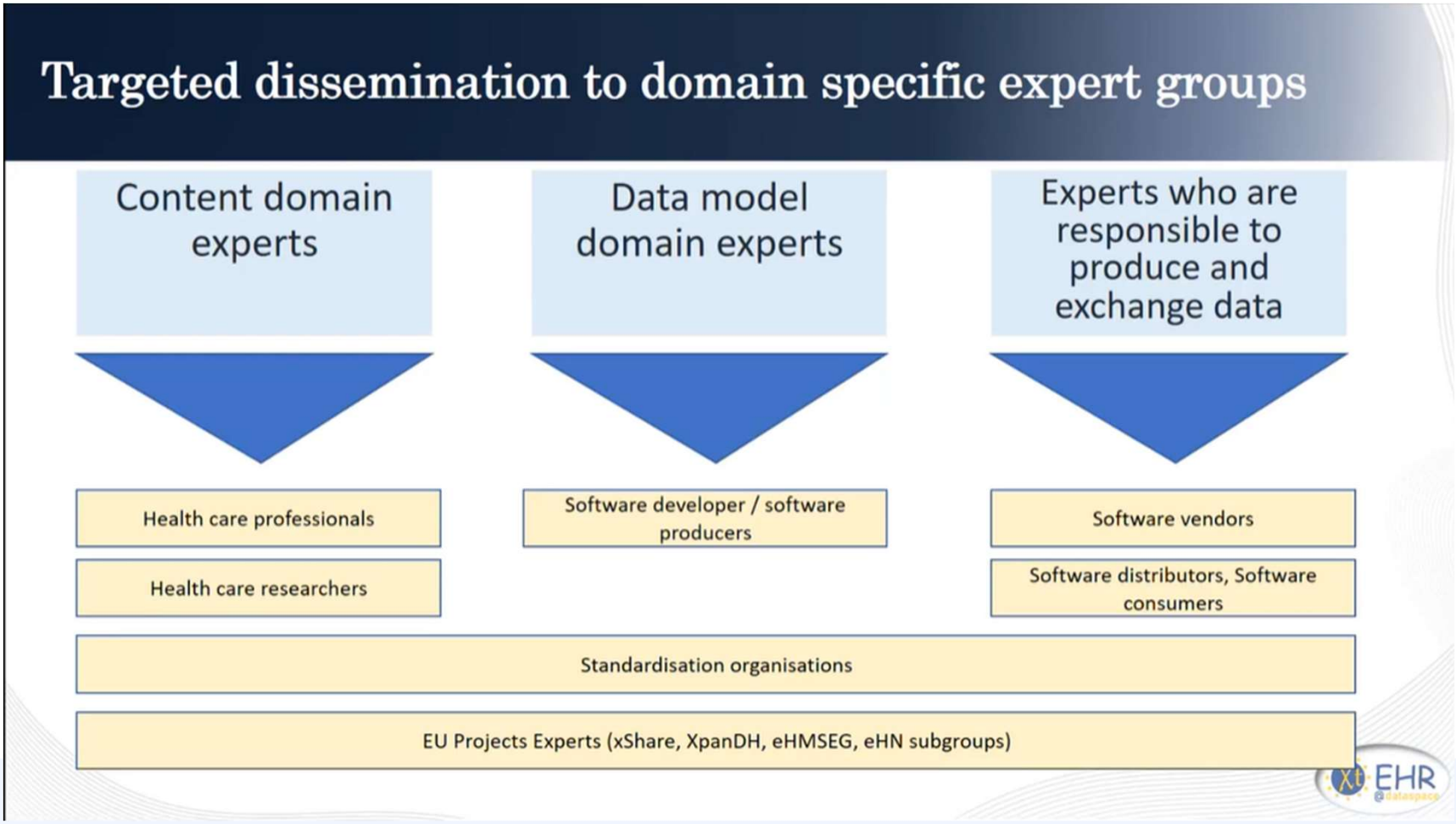
2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

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

Utvikling av nye spesifikasjoner og tjenester



Nasjonal involvering



Samarbeidsmodell for internasjonale e-helsestandarder

NUFA (Fagutvalget i nasjonal rådsmodell for e-helse)

Fagdag 29.aug.

Samarbeidsmodell for internasjonale e-helsestandarder

- Standardiseringsutvalget for internasjonale standarder
- European Health Data Space
- Plan for internasjonale standarder
- Helse-NIM

NUFA er et fagutvalg hvor sentrale fagpersoner innen helsefag og arkitektur og innbyggerbehov er representert for å gi råd og vurderinger.

Helsedirektoratet

EHDS-forordningen og krav til EPJ-systemer

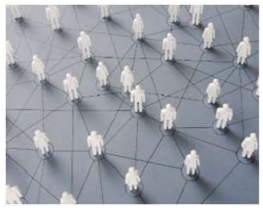
Standardiseringsutvalget

13. Juni 2024

Hva er European Health Data Space - EHDS?

Fastsetter regler, felles standarder, infrastrukturer og et styringsrammeverk for bruk av elektroniske helseopplysninger for helsetjenester, forskning, innovasjon og politikkutforming

PRIMÆRBRUK



Gi innbyggere tilgang til og kontroll over sine helseopplysninger

SEKUNDÆRBRUK

Felles rammeverk for deling og bruk av helsedata til forskning, innovasjon, politikkutforming

Fremme et indre marked for digitale helsetjenester og produkter (EPJ-systemer)

MyHealth@EU infrastrukturen

HealthData@EU infrastrukturen

Status for EHDS forordningsforslaget i EU

Council of the EU | Press release | 15 March 2024 01:10

European Health Data Space: Council and Parliament strike deal

PE-CONS No/YY - 2022/0140(COD)

PUBLIC

REGULATION (EU) 2024/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[8],

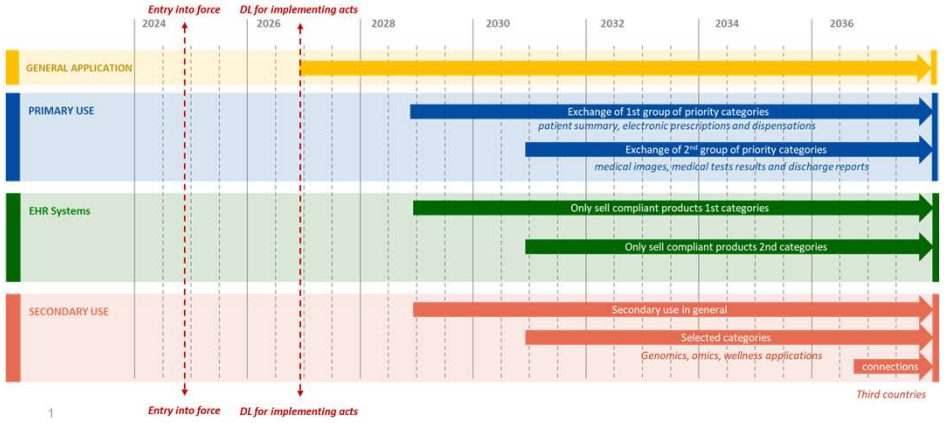
Having regard to the opinion of the Committee of the Regions[9],

Acting in accordance with the ordinary legislative procedure,

- Politisk enighet om innholdet i forordningen
- Korrigendum prosedyre: formelle runder revisjon og oversettelse
- Nytt EU-parlament skal endelig godkjenne
- Publisering i «Official Journal of the EU» og ikrafttredelse i EU forventes høsten 2024
- EØS-behandling starter når forordningen offisielt er vedtatt i EU

Foreliggende EHDS forordningstekst oppsummert

- Hovedlinjene fra opprinnelig forslag fra kommisjonen er intakt
- Største kompromisser:
  - Opt-out sekundærbruk
  - EPJ leverandør sertifiseringssystem
  - Data lokalisering
  - EHDS Board
- Tidslinjen forlenget
- Implementing acts blir viktige!



Implementing acts:

- the European Electronic Health Record exchange Format (EEHRxF)
- common specifications for EHR systems
- digital testing environments for EHR systems
- MyHealth@EU, HealthData@EU
- secure processing environments
- EHDS Board

EHDS og krav til EPJ-systemer

Produsenter av EPJ-system* må oppfylle krav til interoperabilitet, sikkerhet og personvern innenfor prioriterte helsedatakategorier

- 1. gruppe:
  - e-resept
  - pasientoppsummeringer
- 2. gruppe:
  - medisinske bilder
  - lab resultater
  - epikriser

***EHDS definisjon av EPJ-system (Art.2,n):**
'EHR system' (electronic health record system) means any system where the appliance or software allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the priority categories of personal electronic health data as referred to in Article 5(1) of this Regulation and is intended by the manufacturer to be used by healthcare providers in providing patient care or by patient to access to their health data;

Omfang av harmonisering

EPJ-system må ha to harmoniserte komponenter:

- Interoperability component
  - Krav til data import/eksport av prioriterte helsedatakategorier på europeisk EPJ utvekslingsformat – EEHRxF*
- Logging component
  - Krav til logging av hvem som har hatt tilgang til hvilke data og når

Medlemsstatene står fritt til å ha nasjonale krav til andre deler av EPJ-systemet, så lenge det ikke påvirker de harmoniserte komponentene.

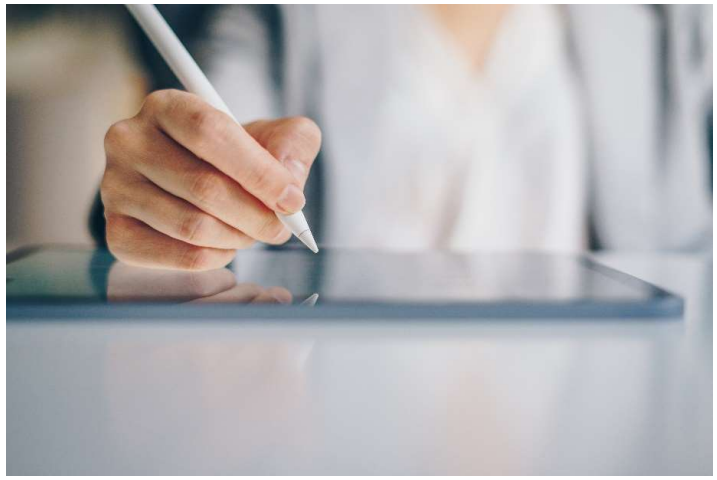
***Europeisk EPJ utvekslingsformat EEHRxF (Art.6):**
Et sett med tekniske spesifikasjoner som skal sikre interoperabiliteten til elektroniske journalsystemer som brukes på det europeiske marked.

Selvdeklarering med en tvist

- Produsenter må gjøre selvdeklarering og gjennomføre obligatorisk test i automatisert testmiljø
- Kommisjonen skal tilrettelegge for testmiljøet
- Produsenter må teste harmoniserte komponenter av produkter før de markedsføres og inkludere testresultater
- Publiseres i EU database med oversikt over systemer som oppfyller EU krav
- Market surveillance authority

Krav til helseapper / livsstilsapplikasjoner

- Merking av helseapper / livsstilsapplikasjoner som hevder å ha interoperabilitet med EPJ-system
- I relasjon til de harmoniserte komponenter
  - Interoperabilitet (prioriterte kategorier)
  - Logging



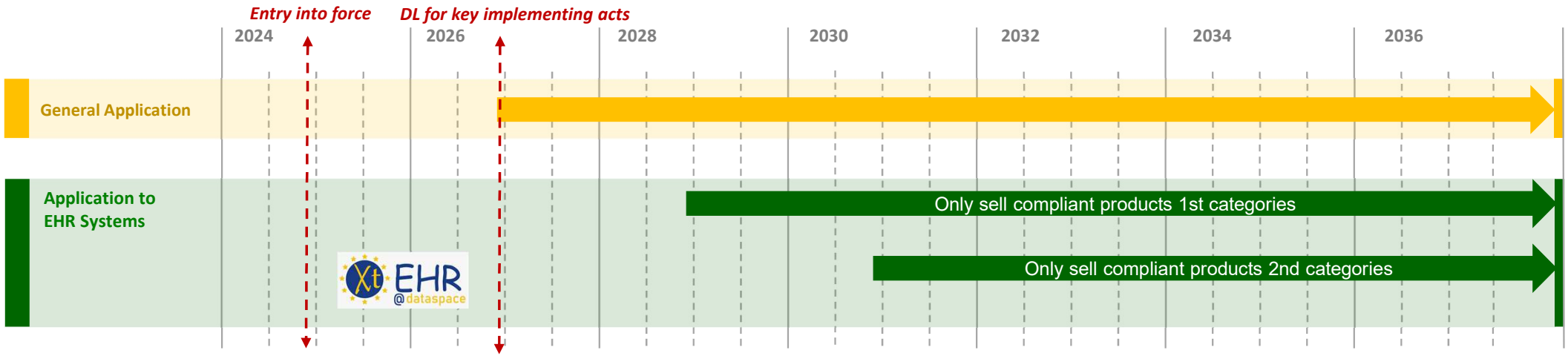
- Registreres i EU database

LABEL2ENABLE

CEN-ISO/TS 82304-2:2021 Health and wellness apps – Quality and reliability

Xt EHR @dataspace

Fremdrift



- Spesifikasjoner for harmoniserte komponenter og test miljø skal være tilgjengelig 2 år etter forordningen trer i kraft (dvs. høst 2026)

- Ytterligere 2 år (2028) til selvdeklareringsordningen får virkning for første produktkategorier, 4 år (2030) til andre gruppe av produktkategorier

EHDS konsekvens- og mulighetsanalyse

Under arbeid

> 06. 2024	2025	2026

Fase 1:

Gap-analyse

- Identifisere gap mellom hvor vi er i dag og EHDS krav
- Oversikt nasjonale veivalg
- Alternative tiltak
- Kostnadsdrivere
- Kostnadsspenn
- Rådsmodell og rundebordsmøter per arbeidsspor

Fase 2:

Anbefale tiltak

- Positive og negative virkninger av tiltak
- Involvere sektor i drøfting og vurdering av tiltak
- Undersøke i andre land
- Anbefale tiltak

Fase 3:

Veikart

- Utarbeide plan for realisering
- Prioritering ifht nasjonal portefølje

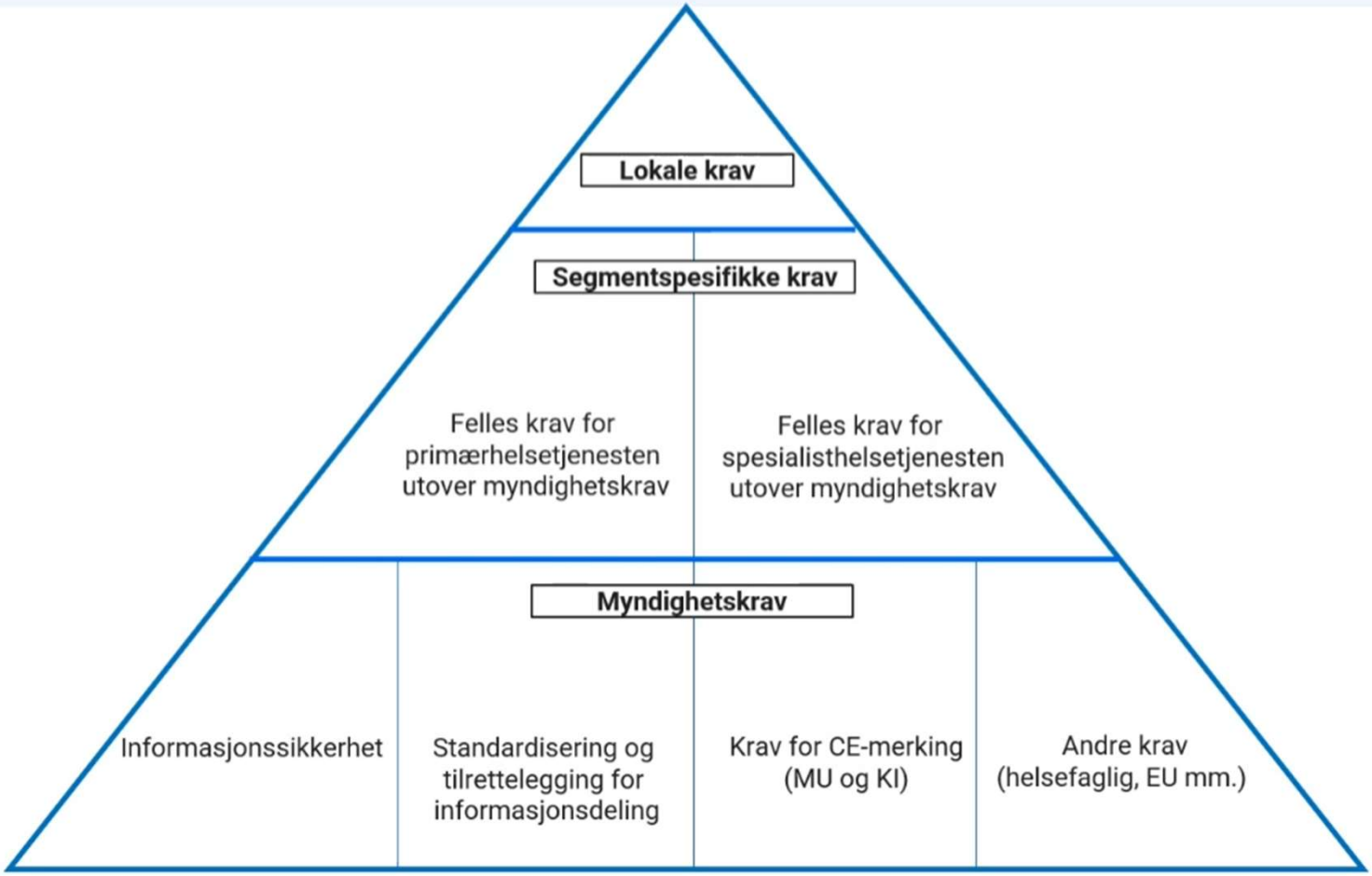
Arbeidsspor:
#1: Innbyggers rettigheter
#2: Datautveksling primærbruk
#3: Krav til leverandørmarkedet
#4: Datautveksling sekundærbruk
#5: Governance

eHealth Network workshops

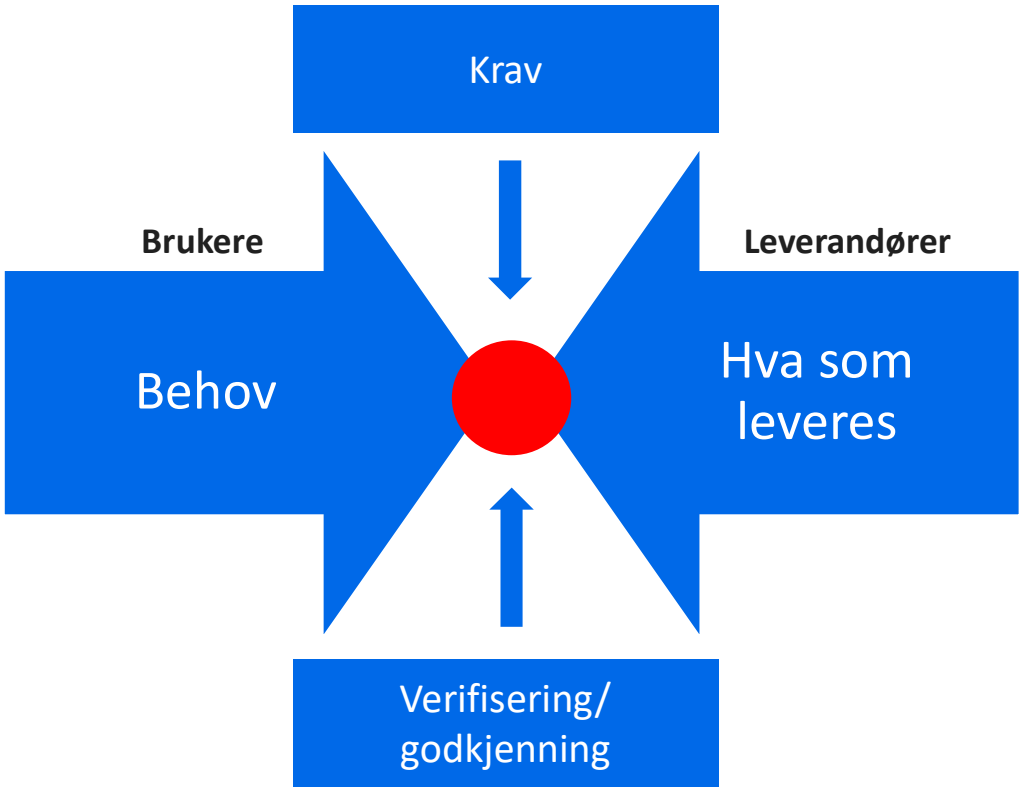
Xt-EHR og TEHDAS2 - Innspill til implementing acts (IA)

COM ferdigstiller IA

Mulig modell - kravpyramiden



Andre relevante tiltak i helseteknologiordningen



- **Veiledningstjenester og godkjenningsordninger** som sikrer felles tolkning av krav og verifisering av disse
- **Samarbeid** mellom statlige og private aktører om felles modeller for å oppnå dette

Diskusjon

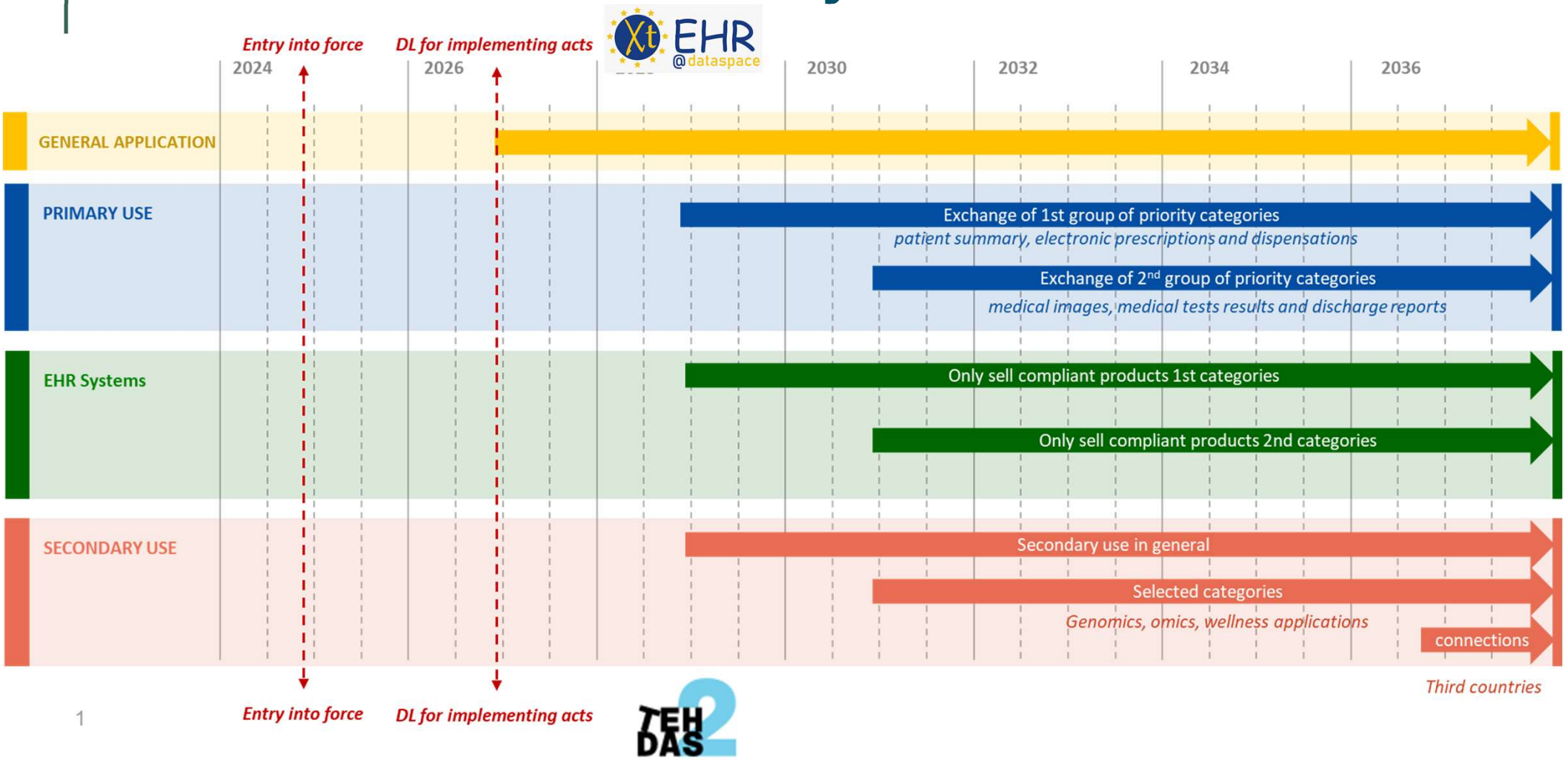
- Hvilken betydning vil EHDS-forordningen kunne få for det norske journalleverandørmarkedet fremover?
- Hvilke konsekvenser og muligheter ser dere?

Helsedirektoratet

Takk for oppmerksomheten!

Marianne Bårtvedt van Os – marianne.bartvedt.van.os@helsedir.no

EHDS – Overordnet tidslinje



Xt-EHR Work package 8: Certification and labeling framework

Scope of Work Package 8:

- Establish Assessment Framework: Develop a framework for assessing the interoperability of EHRs, personal health data spaces, and wellness applications.
- Prepare Guidelines for Wellness Apps: Provide guidelines for app developers based on EHDS regulations and ISO/TS 82304-2.
- Evaluate Previous Initiatives: Assess results from previous initiatives (e.g., Label2Enable, EuroCAS) to inform the development of guidelines and assessments.

  - 8.1 Classification and functional profiles of **EHR systems** guidelines (doc.)
  - 8.2 EHR Conformity Assessment Scheme assertion document and checklists (doc.)
  - 8.3 **Wellness application** labelling guidelines (doc.)

Helsedirektoratet

Lunsj

Tilbake 12:45

Helsedirektoratet

ExpanDH goes to Norway

Henrique Martins - FCB-UBI, ISCTE-IUL

XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Helsedirektoratet

Welcome!

XpanDH goes to Norway (online participating in the "Standardiseringsutvalget for internasjonale e-helsestandarder" event, 13 June 2024

Funded by the European Union

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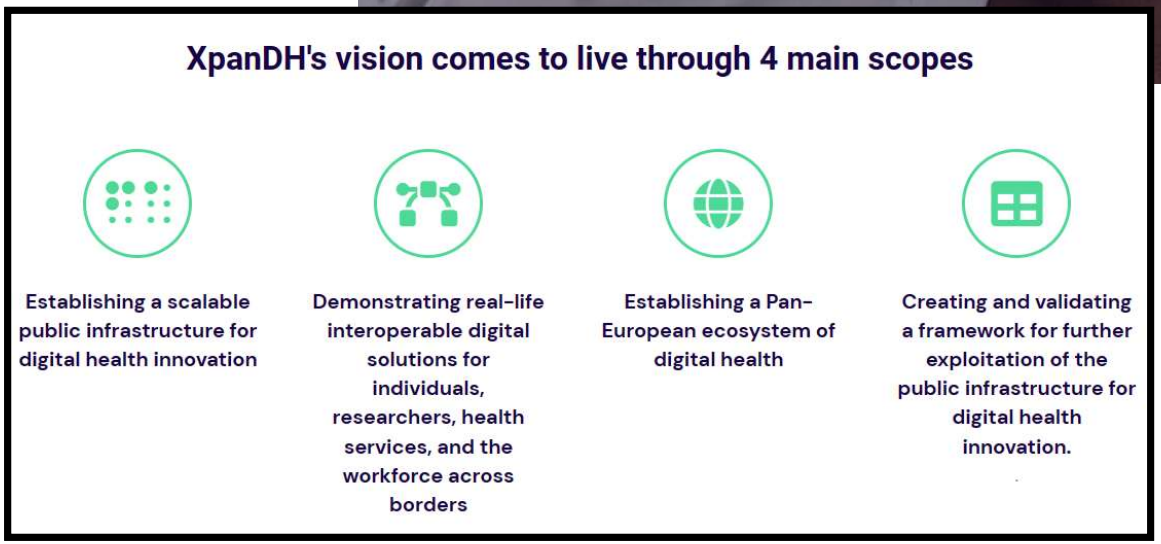
XpanDH Project

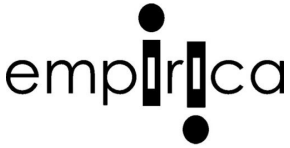
Coordinator:
Henrique Martins
Project manager:
Anderson Carmo
2023-2024



https://xpandh-project.iscte-iul.pt/

Funded by the European Union

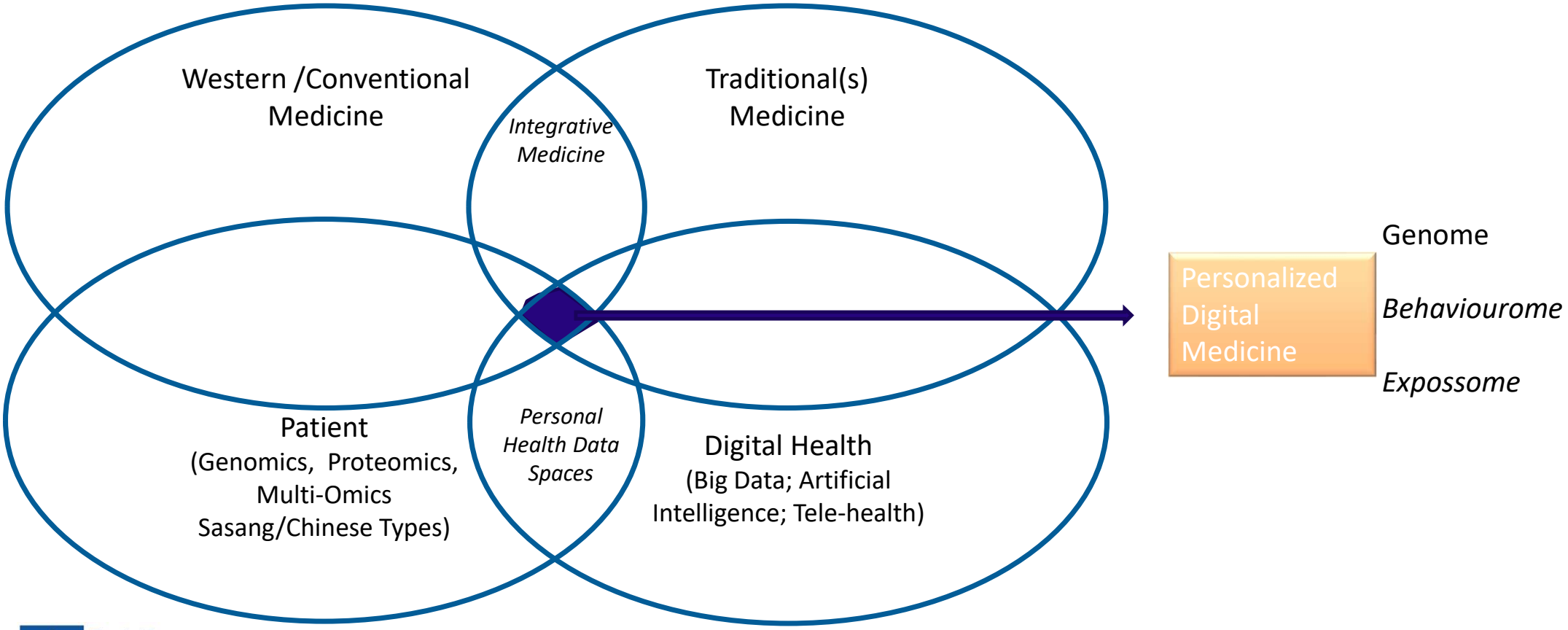
XpanDH is a consortium with 28 partners



edha - european digital health academy gGmbH

New “Integration” paradigm: the (digital) patient

(Integrative Medicine = Conventional + Traditional Medicine)



Funded by the European Union

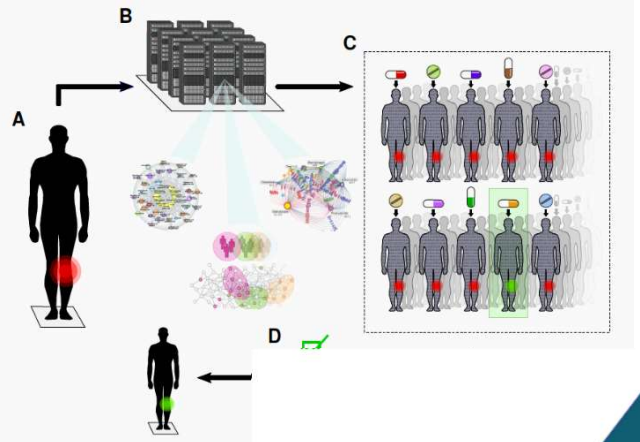
The (digital twin) patient _ Personal Health Data Space

Figure 1. The digital twin concept for personalized medicine (from Björnsson et al. Genome Medicine).

A) An individual patient with a local sign of disease (red).

B) A digital twin of the patient is constructed in unlimited copies, based on high-performance computational integration of thousands of disease-relevant variables.

C) Each twin is computationally treated with one or more of thousands of drugs. This results in digital cure of one patient (green). D) The drug that has the best effect on the twin is selected for treatment of the patient.



https://www.sdtc.se/

Digital twins is a concept from engineering, which has been applied complex systems such as airplanes or even cities The key idea is to computationally model those systems, in order to develop and test them more quickly and economically than in real life. STDC aims to apply this concept to personalize medicine, by constructing 1) network models of all molecular, phenotypic and environmental factors relevant to disease mechanisms in individual patients (digital twins); and 2) computationally treat those twins with thousands of drugs in order to identify the best one or ones to 3) treat the patient (Figure 1).

People Centric Model to Harness User Value

Reflection on Personal Data Spaces in Transformation of Health and Care

Anne Moen I Professor I University of Oslo and Norwegian Center for eHealth Research I Norway
Catherine Chronaki I Secretary General I HL7 Europe I Belgium
Henrique Martins I Associate Professor I ISCTE Business School I ISCTE-IUL, Lisbon I Faculty of Health Sciences I Universidade da Beira Interior I Covilhã, Portugal
Giovanna Ferrari I Regional Labeling Lead I Global Regulatory Affairs I Global Product Development I Pfizer Limited I UK

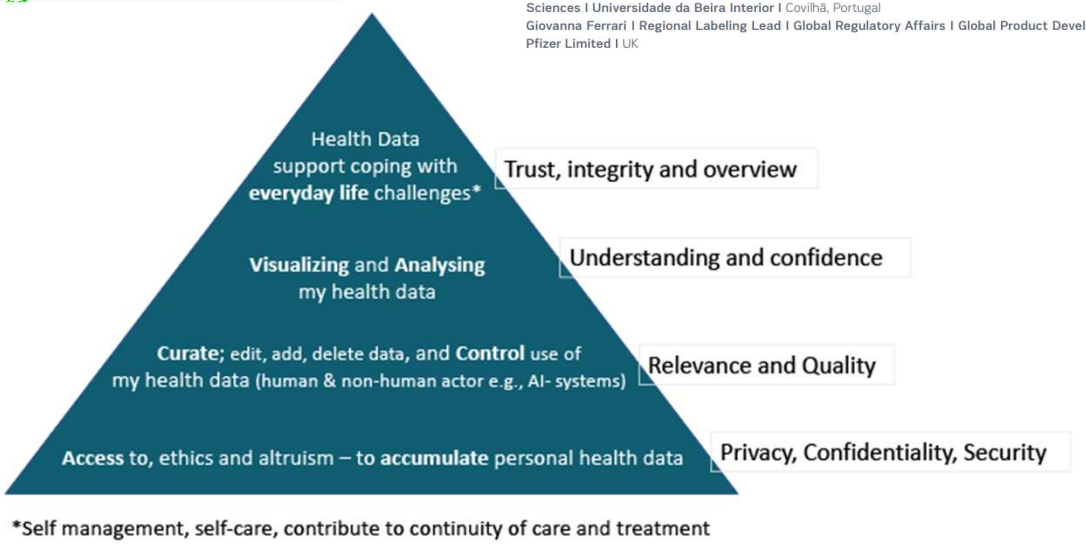


Figure 1.: Personal Health Data Space

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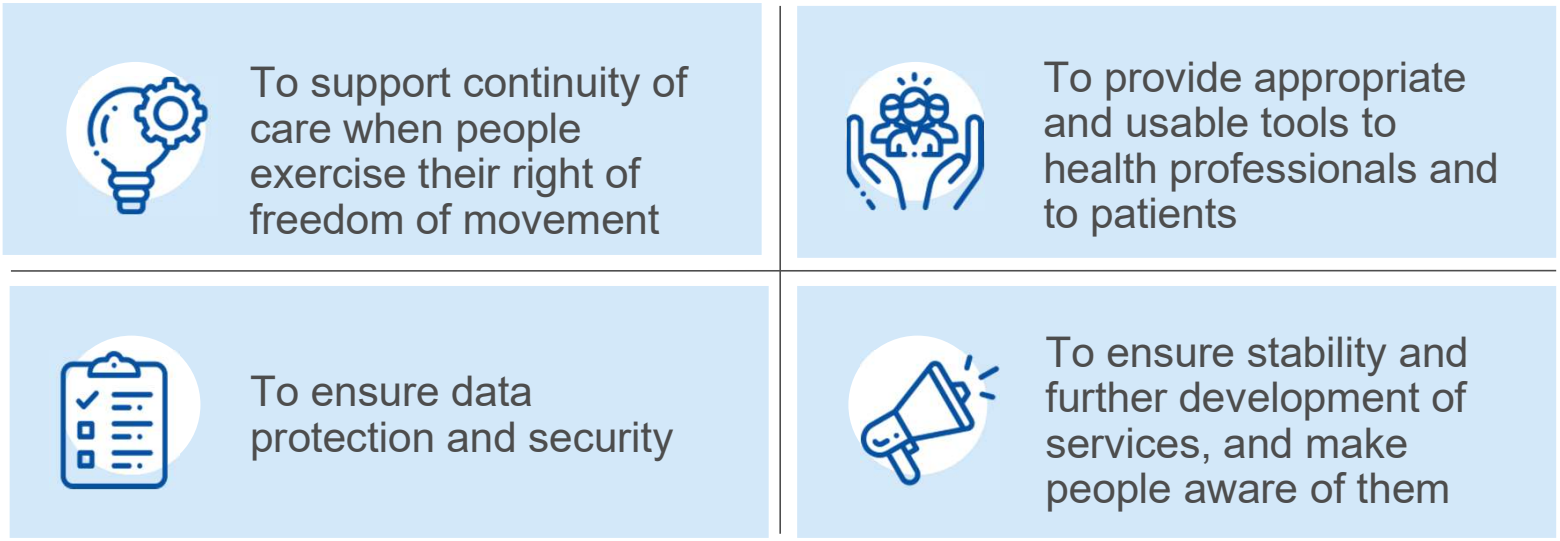
My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

MyHealth@EU – the current cross-border infrastructure for digital health

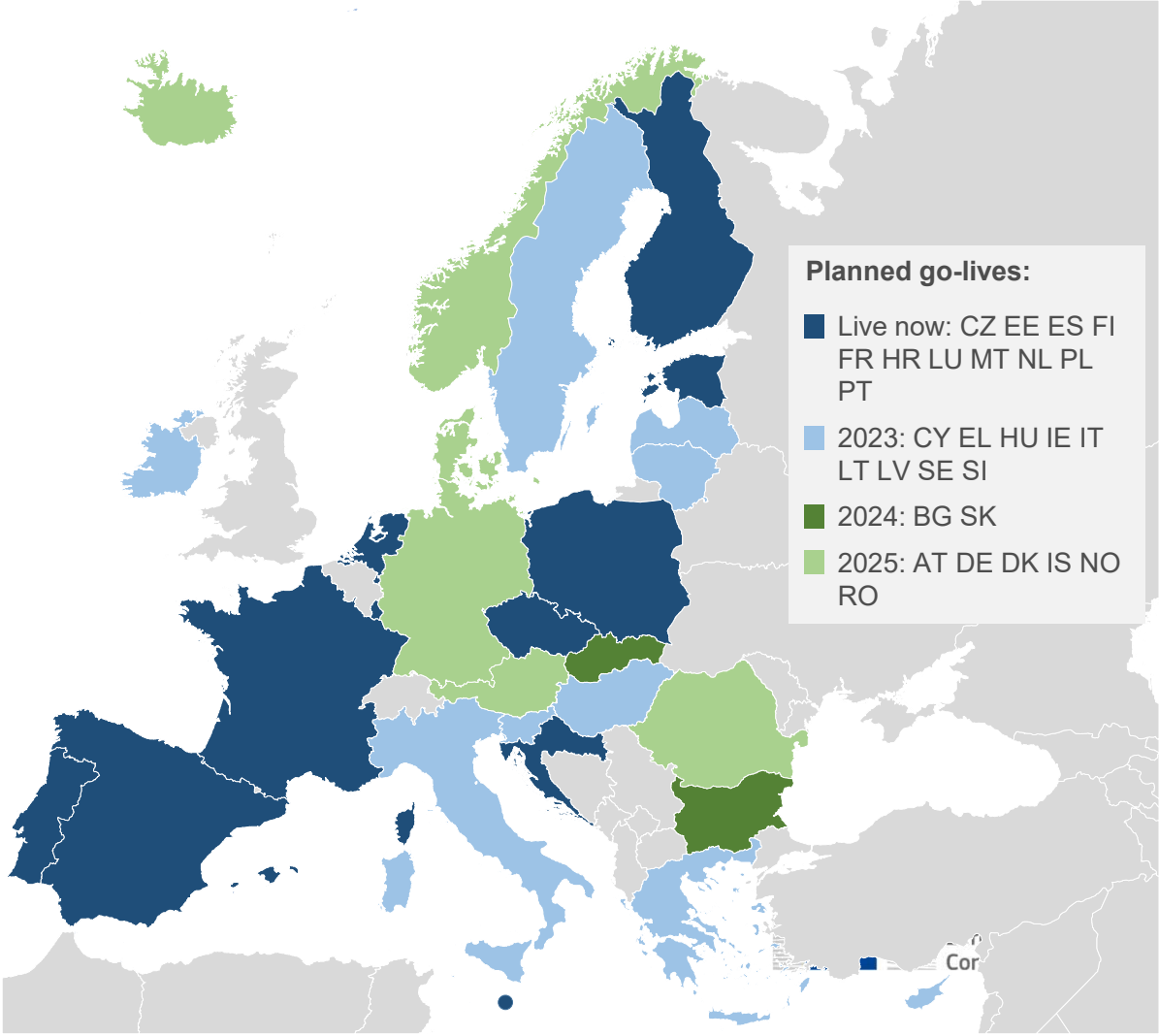


MyHealth@EU state of play

MyHealth@EU is the existing infrastructure that connects healthcare providers in 11 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.



Cross-border e-Prescription in action

My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

Illustration based on materials from: THL/FI

European Context

- Commission Communication "A European Strategy for data" (
- DigitalHealthEurope (www.digitalhealtheurope.eu) recommendations (incl. "Health Data Activism") (Sept 2021)
- Data Governance Act (Nov 2021-16.may.2022)**
  - **Data altruism for the common good** The DGA also makes it easier for individuals and companies to **make data voluntarily available for the common good**, such as medical research projects.
- Data Act (proposed regulation 23.02.2022)***
  - Regulation on harmonised rules on fair access to and use of data (IoT/etc)
- NEW proposal on the Regulation on a European Health Data Space (3.may.2022) *** - TO BE VOTED 24.04.2024
- Future NIS Directive ("CyberSecurity") – NIS2 (16.12.2020) – Political agreement (13.05.2022) –

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* A European Strategy for data" https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066
** https://www.consilium.europa.eu/pt/press/press-releases/2022/05/16/le-conseil-approuve-l-acte-sur-la-gouvernance-des-donnees/
*** - https://digital-strategy.ec.europa.eu/en/library/data-act-proposal-regulation-harmonised-rules-fair-access-and-use-data
**** - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022PC0197&from=EN

XpanDH

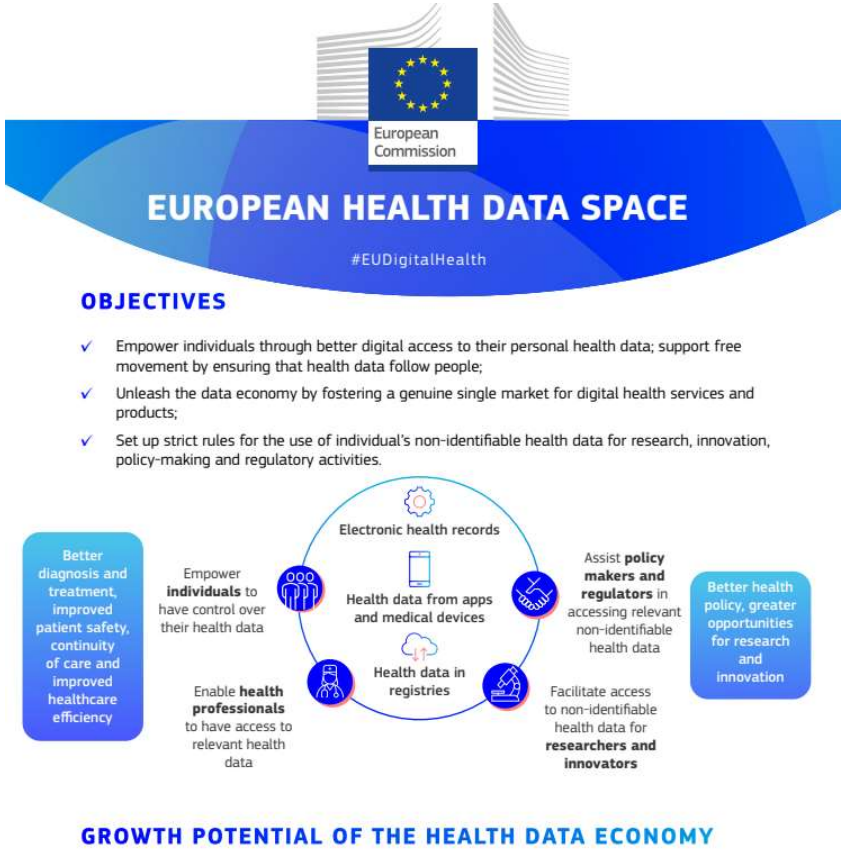
European Health Data Space Regulation (approved EP 24.4.24)

Funded by
the European Union

XpanDH landscape and project vision

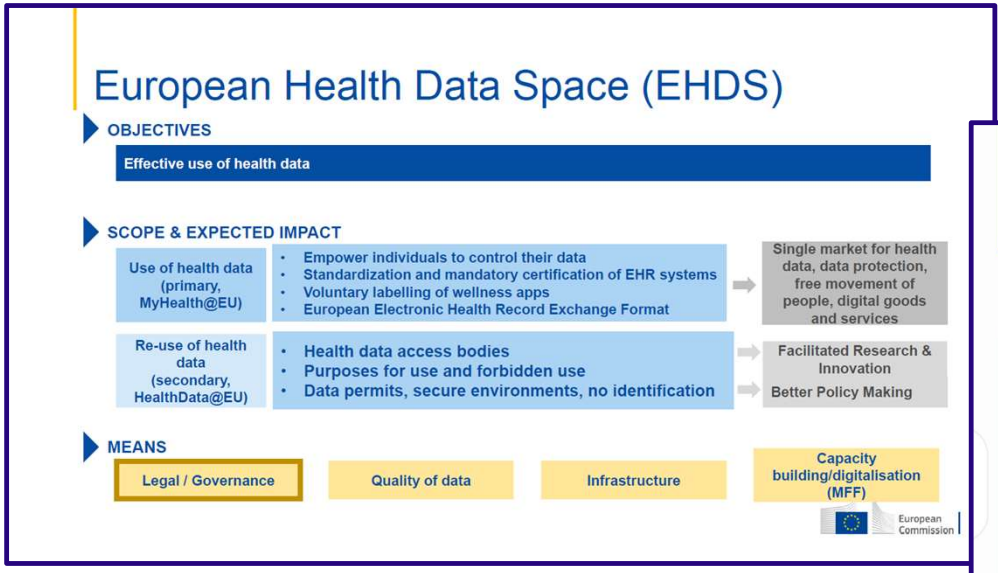
In that context the **EC is building up a regulation proposal** about the ***European Health Data Space*** **– EHDE** with some key statements:

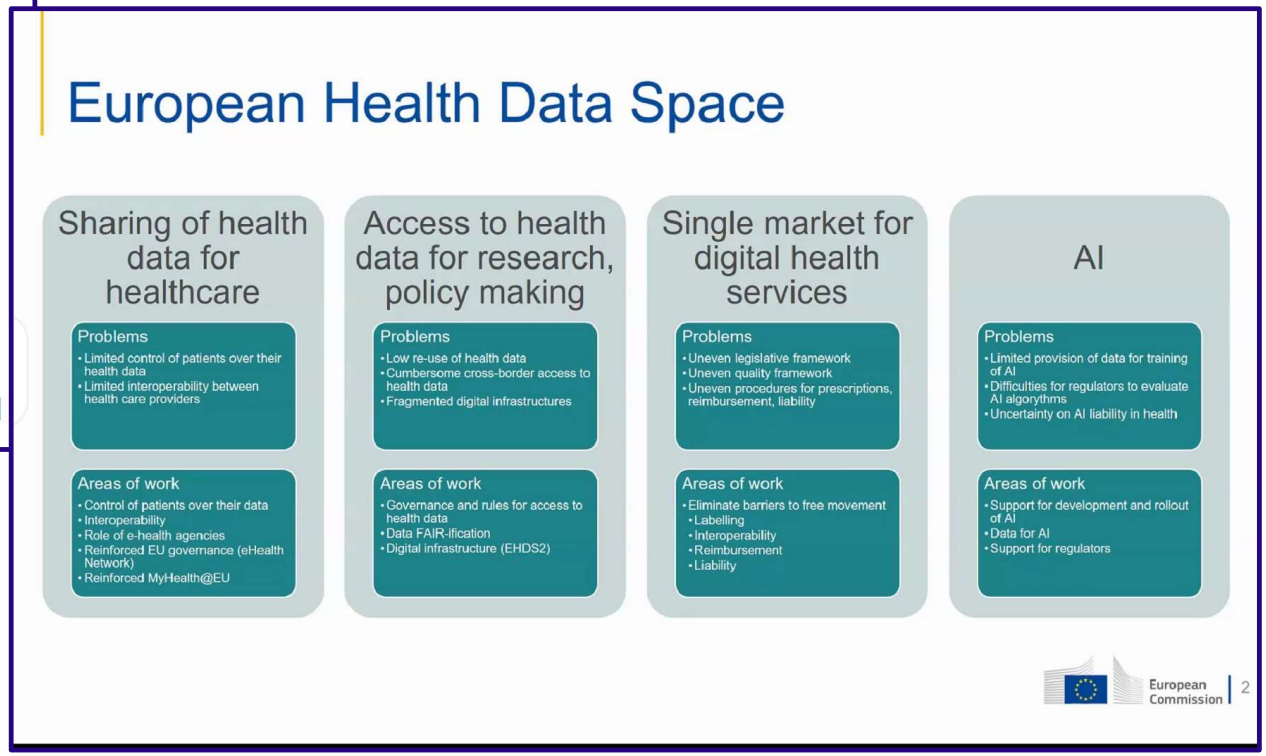
- "**requirements** that have been imposed on **software** through the **Medical Devices** Regulation"
- "regulatory gap has been identified when it comes to **information systems used in the health domain**, also called electronic health record systems (**EHR systems**)"
- "the EDHS sets **essential requirements specifically for EHR systems** in order to **promote interoperability and data portability**"



Funded by the European Union

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework





Funded by the European Union

The EHDS – Chapter I; Article 1

Subject matter and scope

1. This Regulation establishes the European Health Data Space ('EHDS') by providing for common rules, standards, infrastructures and a governance framework with a view to facilitating access to electronic health data for the purposes of primary and secondary use of these data.

2. This Regulation:

(a) specifies and complements the rights laid down in Regulation (EU) 2016/679 of natural persons in relation to the primary and secondary use of their personal electronic health data;

(b) lays down common rules for electronic health records systems ('EHR systems') in relation to two mandatory software components, namely the 'European interoperability component for EHR systems' and the 'European logging component for EHR systems' as defined in Article 2(2), points (nc) and (nd), and wellness applications that claim interoperability with EHR systems in relation to those two components in the Union for primary use;

(c) lays down common rules and mechanisms for primary and secondary use of electronic health data;

(d) establishes a cross-border infrastructure enabling the primary use of personal electronic health data across the Union;

(e) establishes a cross-border infrastructure for the secondary use of electronic health data;

(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.

Funded by the European Union

Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – Chapter II; Article 5 n.1

Priority categories of personal electronic health data for primary use

1. For the purposes of this Chapter, where data is processed in electronic format, the priority categories of personal electronic health data shall be the following ▌:

(a) patient summaries;
(b) electronic prescriptions;
(c) electronic dispensations;
(d) medical imaging studies and related imaging reports;
(e) medical test results, including laboratory and other diagnostic results and related reports;
(f) discharge reports.

The main characteristics of the priority categories of personal electronic health data ▌shall be as set out in Annex I.

Member States may provide by virtue of national law that additional categories of personal electronic health data shall be accessed and exchanged for primary use pursuant to this Chapter. The Commission may, by means of implementing acts, lay down cross-border specifications for these data categories pursuant to Article 6(-1a) and Article 12(8).

(2022 PROPOSED TEXT). (d)medical images and image reports; (e) Laboratory results;

Funded by the European Union

Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – ANNEX I

Main characteristics of **priority categories of personal** electronic health data **for primary use**

Electronic health data category	Main characteristics of electronic health data included under the category
1. Patient summary	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems ***including in an international classification coding*** 8. Textual information related to medical history 9. Medical devices and implants 10. ***Medical or care*** procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease
2. Electronic prescription	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.
3. Electronic dispensation	Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.
4. Medical image and image report	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.
5. Laboratory result	Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.
6. Discharge report	Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – Chapter II; Article 5 n.2

Priority categories of personal electronic health data for primary use

2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend ▌ Annex I by adding, modifying or removing the main characteristics of the priority categories of personal electronic health data as referred to in paragraph 1. The amendments shall satisfy the following **cumulative** criteria:

(a) the characteristic is relevant for healthcare provided to natural persons;

(b) the characteristic as modified is used **in the majority of** Member States according to the most recent information;

(c) the changes are aimed to adapt the priority categories to the **technical evolution and international standards**.

(2022 PROPOSED TEXT). The categories of electronic health data added through such delegated acts shall satisfy the following criteria:

(a)the category is relevant for health services provided to natural persons;

*(b)according to the most recent information, the category is used in **a significant number** of EHR systems used in Member States;*

(c)international standards exist for the category that have been examined for the possibility of their application in the Union.

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – Chapter II; Article 6 n.1

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(1), setting out the European electronic health record exchange format. Such format **shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. The format should support transmission of structured and unstructured health data**. The format shall include the following elements:

(a) harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the ▌ 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 interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

Role of implementing acts for EHRxF adoption

1. **Detailed Provisions**: Implementation acts will provide specific details and technical specifications necessary for the regulation's effective execution. This includes defining standards, formats, and procedures to ensure interoperability and secure data exchange across the EU.
2. **Operational Guidelines**: They will offer operational guidelines for the functioning of EHDS entities, such as data access bodies and health data access points. This ensures a harmonised approach across member states, promoting consistent and efficient data usage.
3. **Compliance and Monitoring**: Implementation acts will establish mechanisms for monitoring compliance with the EHDS regulation. They will set up procedures for regular reporting, auditing, and evaluation to ensure that the objectives of the EHDS are being met.
4. **Adaptability**: These acts allow for the regulation to be updated and adapted in response to technological advancements and emerging challenges. This ensures that the EHDS remains relevant and effective over time.

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SOME of the Foreseen implementing acts to come

EHDS Regulation	Aims & scope
Article 3	Determine the requirements for the technical implementation of the rights set out in Section 1.
Article 5	Lay down cross-border specifications for mentioned data categories. To amend Annex I by adding, modifying or removing the main characteristics of the priority categories
Article 6	Lay down the technical specifications for the priority categories of personal electronic health data setting out the European EHRxF.
	Provide regular updates of the European EHRxF to integrate relevant revisions of the healthcare coding systems and nomenclatures.
	Lay down technical specifications that **extend the European EHRxF to additional categories** of electronic health data.
Article 7	Determine data quality requirements, including semantics, uniformity, consistency of data registration, accuracy and completeness, for the registration of personal electronic health data in EHR system.
Article 8aa	Lay down the technical specifications to ensure the interoperability of the proxy services of the Member States.

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XpanDH

What is it, a “format”?

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European EHR Exchange Format Definition

The Format definition

The **European Electronic Health Record Exchange Format** (or "The Format") is a **set of requirements and technical specifications**, as well as endorsed support materials, **targeted at ensuring the interoperability of electronic health record systems** following the Regulation on the **European Health Data Space** and other applicable law. It is designed to **enable the exchange of personal electronic health data** between two or more EHR systems, other digital health applications or medical devices **and support interoperable capture and reuse in a meaningful way**.

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Which of the following are “formats”?

eHN Patient Summary Guidelines v 3.1

International Patient Summary (EN ISO 27269:202)

IPS FHIR Implementation Guide

CDA Implementation Guide for Patient Summary in MyHealth@EU, Wave 6

HL7 FHIR | HL7 FHIR R4 | HL7 CDA

IHE Patient Care Coordination (PCC) CDA Content Modules

JSON | XML

PDF (ISO 32000)

A Patient Summary can be represented using any of these

Level of detail varies significantly

Not all provide direct instructions to implement

Not all are interoperable at the level of structured data

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Some useful features of data exchange formats

- The format should be publicly available
  - Preferably, free of charge to all users
  - The public availability of the format does not mean that third parties may not provide commercially tools, support and consultation associated with the use of the format
- The format should be developed through a collaborative process ensuring the involvement of end users
  - Possible groups of end users: patients, health professionals, developers, and research organisations
- The format should be implementable
  - Its descriptions should be sufficiently detailed, prescriptive, and unambiguous
  - The risk of different interpretations could lead to decreased interoperability of electronic health record systems using the format should be minimised

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XpanDH

XpanDH Project Overview

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XpanDH scope

XpanDH is focused in **4 main scopes** to operationalise their vision:

1. E**stablishing and sustaining** a scalable public **infrastructure** for **digital health innovation**

2. **Demonstrating feasibility of real-life interoperable digital solutions** for use by individuals, researchers, health services and the workforce across borders (X-bubbles)

3. **Establishing** and sustaining a **Pan-European ecosystem** of digital health

4. **Creating** and validating a **framework** for enabling further exploitation of the public infrastructure **for digital health innovation**

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Main objectives

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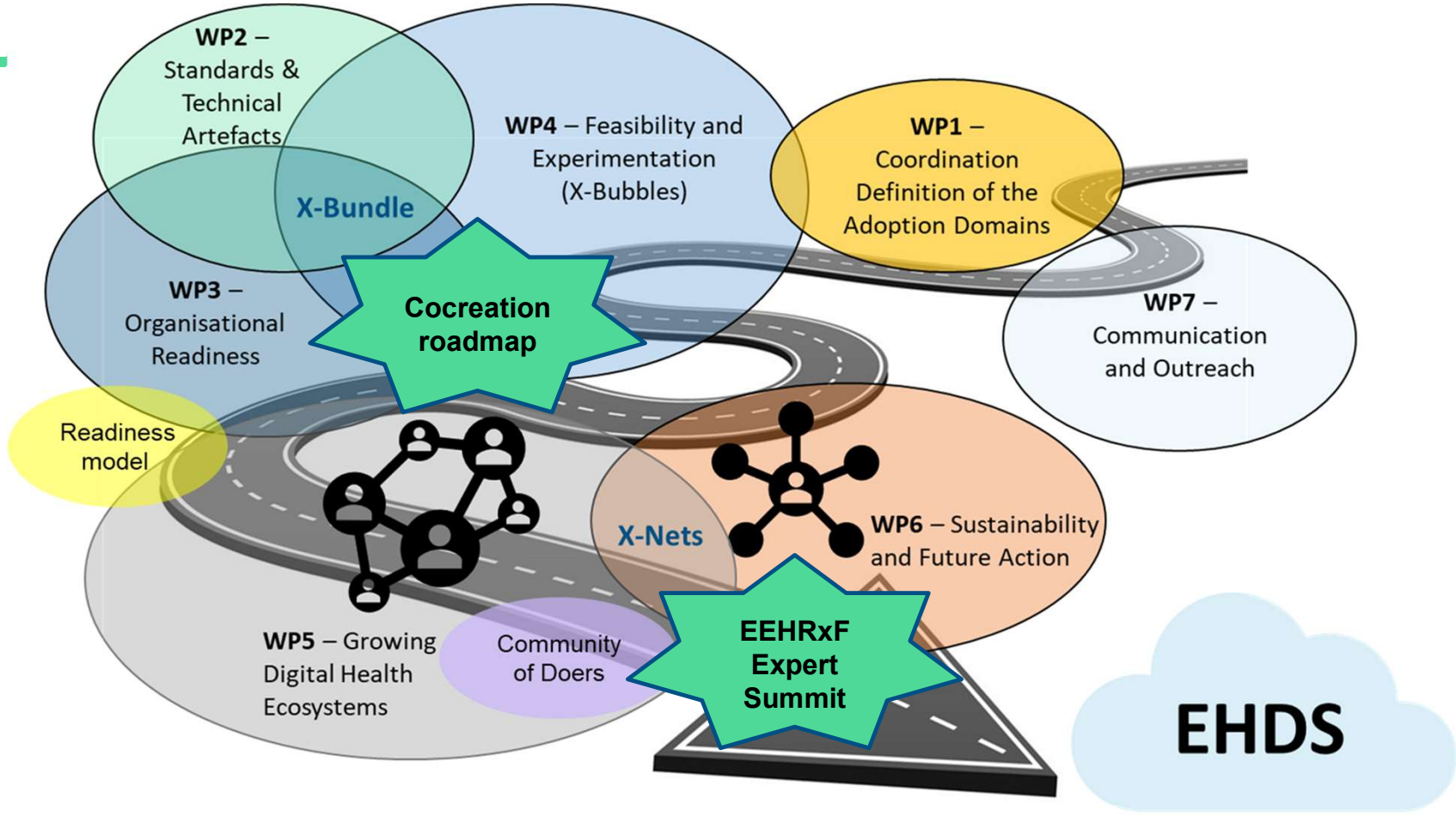
Project Overview



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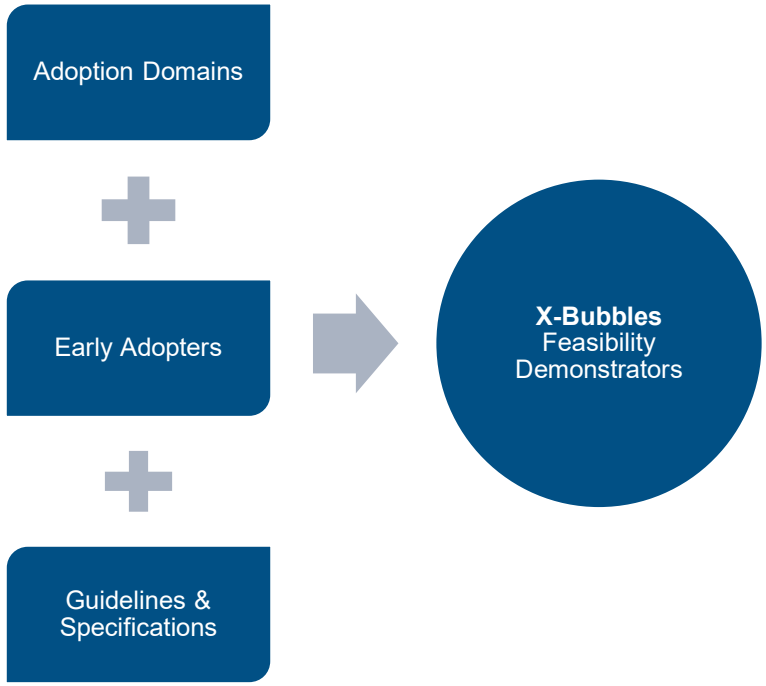
WP4 Objectives

- Demonstrate feasibility in real-world experimentations with a set of EEHRxF early adopters' organisations grouped under selected adoption domains (X-Bubbles).
- Prove that guidelines and specifications produced are useful, creating conditions for purposeful-use of the EEHRxF in concrete health and care domains.
- Understanding the landscape of EEHRxF adoption as a whole.



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WP4 Bubbles concept

- **X-Bubbles**
  - Groups of organizations that voluntarily test the use of EEHRxF through the definition of concrete use cases for exchange and adoption scenarios.
  - They assess and validate the appropriateness of the format identifying gaps and plan its adoption via feasibility demonstrators.

- **“in silico” Bubbles**
  - Associated partners and other collaborations.
  - Structure exercise around the EEHRxF to identify requirements to the format and its implementation.

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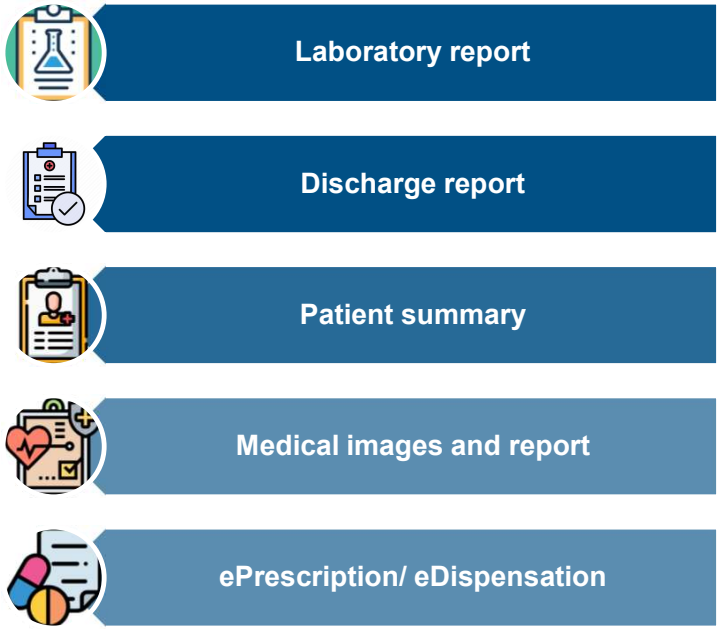
Selection of Specific Adoption Domains
EC priority categories

EEHRxF adoption domain could be considered as an instantiation of a use case, with a specific case application, that has meaning from a health system or clinical perspective, with defined implementable requirements, that satisfies all the conditions for users to be ready to implement data exchange in conformity to EEHRxF guidelines and specifications.



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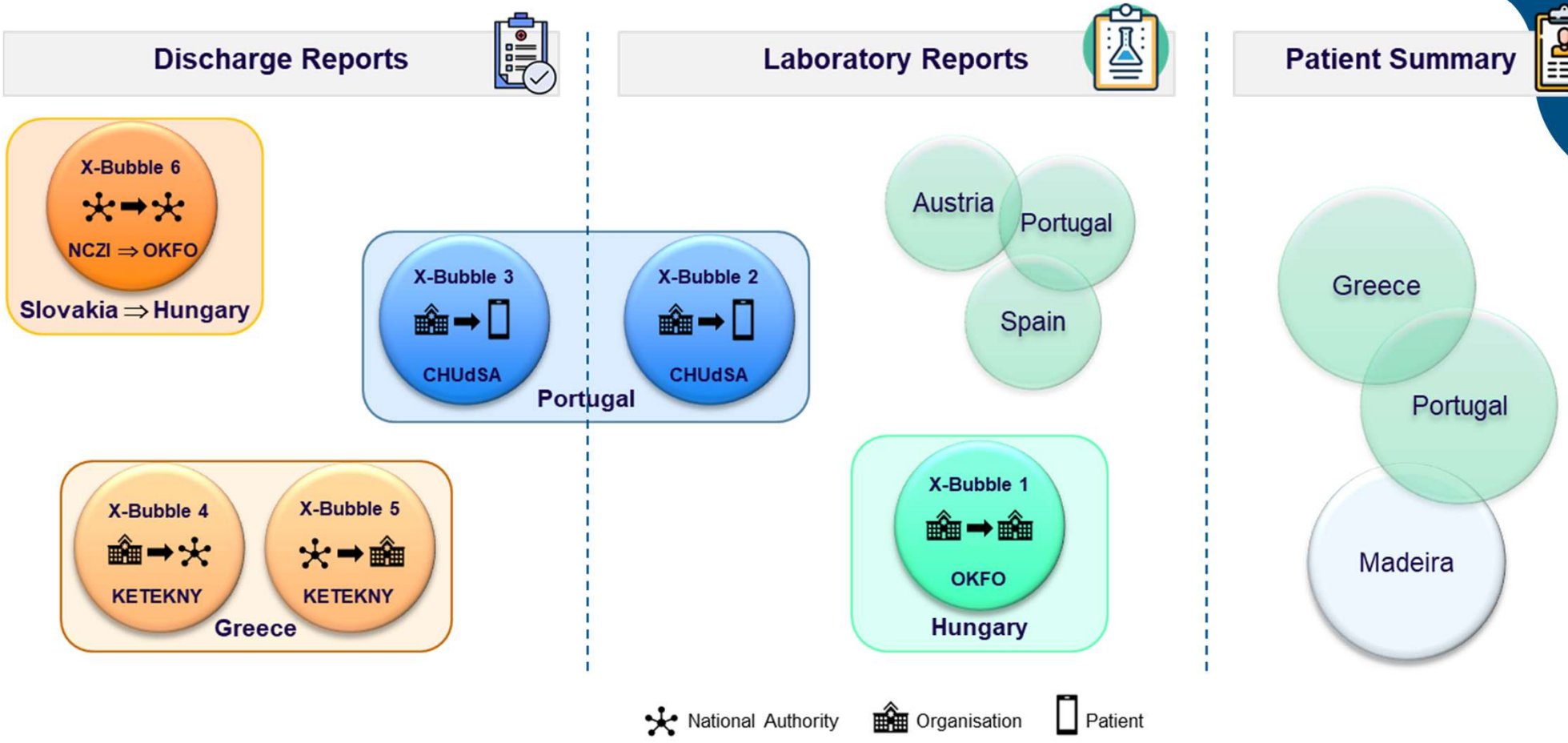
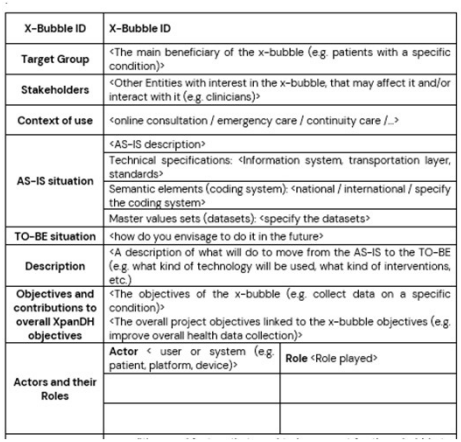
X-Bubbles: current and being prepared



T4.1 – Preparing the experimentation bubbles (M01 – M20)

- Bilateral meetings with X-Bubbles to define use cases → D4.1
  - Motivation and objectives
  - Context of data exchange
  - Current situation: AS-IS
  - Future situation: TO-BE



X-Bubble ID	X-Bubble ID	
Target Group	<The main beneficiary of the x-bubble (e.g. patients with a specific condition)>	
Stakeholders	<Other Entities with interest in the x-bubble, that may affect it and/or interact with it (e.g. clinicians)>	
Context of use	<online consultation / emergency care / continuity care /...>	
AS-IS situation	<AS-IS description>	
	Technical specifications: <Information system, transportation layer, standards>	
	Semantic elements (coding system): <national / international / specify the coding system>	
	Master values sets (datasets): <specify the datasets>	
TO-BE situation	<how do you envisage to do it in the future>	
Description	<A description of what will do to move from the AS-IS to the TO-BE (e.g. what kind of technology will be used, what kind of interventions, etc.)>	
Objectives and contributions to overall XpanDH objectives	<The objectives of the x-bubble (e.g. collect data on a specific condition)> <The overall project objectives linked to the x-bubble objectives (e.g. improve overall health data collection)>	
Actors and their Roles	**Actor** < user or system (e.g. patient, platform, device)>	**Role** <Role played>

- Alignment meetings with EC

- Workshops:
  - 2 X-bubbles workshops: Laboratory report and Hospital Discharge Report
  - EEHRxF co-creation and national experimentation: CZ, PT, BE, NL
  - Exploratory workshop with associated partners: Laboratory Report and Patient Summary

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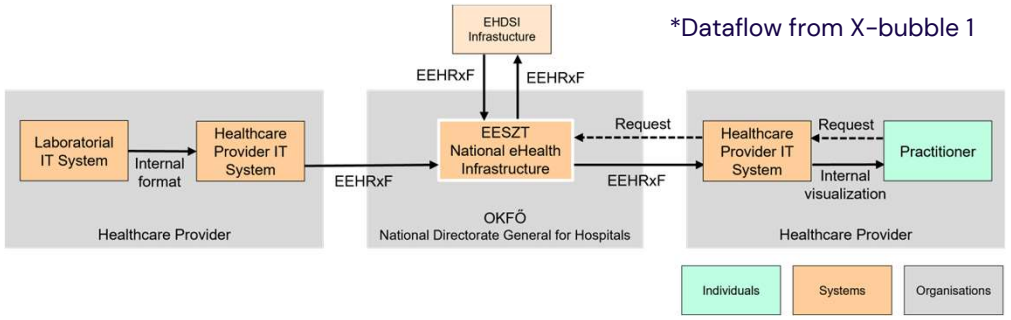
T4.2 - EHRxF-based infrastructure (X-Bundle) feasibility demonstration (M06-M21)

- Development and handover of *D4.3 – D4.2 XpanDH feasibility demonstrators (M14)*

- Detailed analysis of each X-Bubble
  - Understand the existing methods for data exchange
  - Analyse internal formats/systems
  - Identify requirements for possible implementation

- Bilateral meetings with X-Bubbles
  - Review and analysis of eHN guidelines
  - Definition of high-level data flows
  - Definition of demostrator plans



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T4.2 – EHRxF-based infrastructure (X-Bundle) feasibility demonstration (M06–M21)

- Deep analyse of eHN guidelines to provide concrete insight in:
  - Data types
  - Cardinalities
  - Code systems
  - Value sets

Field	Bubble 1 Hungary	Bubble 2 Portugal	Field	Bubble 1 Hungary	Bubble 2 Portugal
A.1 Report header data elements			A.1.8 Laboratory report metadata (9)	4 required 4 optional 1 not required	6 required 3 optional
A.1.1 Identification of the patient/subject (5)	4 required 1 optional	5 required	**A.2 Order information (6)**	6 optional	4 required 2 optional
A.1.2 Patient/subject related contact information (2)	2 optional	2 optional	**A.3 Order reason (1)**	1 optional	1 required
A.1.3 Health insurance and payment information (4)	4 optional	4 optional	**A.4 Specimen information (9)**	9 optional	6 required 3 not required
A.1.4 Information recipient (6)	6 not required	2 required 3 optional 1 not required	**A.5 Results data elements**		
A.1.5 Author (3)	1 required 2 optional	3 required	A.5.1 Laboratory report narrative (2)	1 required 1 optional	2 optional
A.1.6 Legal authenticator (4)	1 required 3 optional	4 not required	A.5.2 Observation details (14)	4 required 8 optional 2 not required	5 required 5 optional 4 not required
A.1.7 Result validator (4)	3 required 1 optional	3 required 1 optional			

eHN gudelines				From de X-Bubbles										
				Organisation to Organisation – bubble 1 – OKFO						Organisation to Patient – bubble 2 – CHUdSA					
#	Field	Field description	Preferred Code System	Required/Optional/Not required	Cardinality	Have this information available? (Y)es / (N)o / (S)tructured	Code System	Value Sets	Comments	Required/Optional/Not required	Cardinality	Have this information available? (Y)es / (N)o / (S)tructured	Code System	VaLue Sets	Comments
A.1 Report header data elements															
A.1.1 Identification of the patient/subject															
A.1.1.1	Family name/surname	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.		Required	1				Name may not be available in structured format	Required	1..1				
A.1.1.2	Given name	The given name/first name of the patient (also known as forename or first name). This field can contain more than one element.		Optional	0..*					Required	1..1				
A.1.1.3	Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Complete date, without time, following the ISO 8601	Required	1		N/A			Required	1..1				
A.1.1.4	Personal identifier	An identifier of the patient that is unique within a defined scope. Example: National ID (birth number) for Czech patient. Multiple identifiers could be provided.		Required	1		type of identifier is proprietary code system issued by Health Insurance		typically SSN is used	Required	1..*				
A.1.1.5	Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere.	HL7 Administrative Gender	Required	1		proprietary code system issued by Health Insurance Fund			Required	1..1				

Aligned – 36 fields
Not aligned – 33 fields

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Example of Experimentation in Laboratory Report

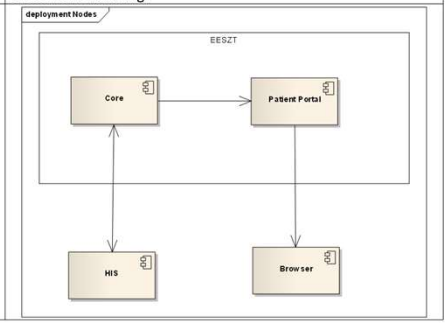
- Organization to Organization – National context

X-Bubble ID	**X-Bubble 1**
Target Group	Diabetes patient
Stakeholders	Clinicians
Context of use	Continuity of care
AS-IS situation	Currently, it is obligator healthcare provider and EESZT to make patient providers treating the his/her data through the Technical specifications: on SOAP for healthcare records pertaining to tl stored as PDF document Semantic elements: Hur ICD-10 for billing purpos Master datasets and providers and heal implementation of ICPM (separate for inpatient and outpatient care), Hungarian implementation of ICD10 and a partial national implementation of LOINC. The PDF is for human use only, no underlying structured document (e.g. EHR according to EN/ISO 13606) is available. The laboratory systems typically use LOINC for internal purposes and use the Hungarian implementation of ICPM for reporting to the health Insurance Fund.

TO-BE situation	Continuity of care for diabetic patients is supported by structured data exchange, saving much time for the physician by providing an integrated view of the patient's condition through time, providing alerts based on the structured data etc.
Description	Necessary steps to move fr 1. The document structu defined. 2. The EESZT interface o has to be updated tc such structured docur 3. The EHR component o validate such structure Note: step 1 is possible with not be possible.
Objectives and contributions to overall XpanDH objectives	Pilot structured data exchar for diabetic patient.

Objectives and contributions to overall XpanDH objectives	Pilot structured data exchange supporting continuity of care for diabetic patient.
Actors and their Roles	**Actor** Physician Patient Laboratc informat EESZT
Preconditions	• Do • EE • Lat an

Trigger	Every time a lab examination is performed in a hospital/outpatient clinic that can create structured lab results.
Flow	1. Physician: uses hospital information system to retrieve already existing structured documents of the patient. 2. Hospital information system: retrieves already existing structured documents of the patient from EESZT. 3. Laboratory and/or hospital information system: sends structured laboratory results to EESZT. 4. EESZT: validates and stores the structured laboratory results, provides access to stored structured documents. 5. Patient: may use the patient portal of EESZT to retrieve structured documents a
Post conditions	Continuity of care documen EESZT.
Requirements	**User requirements** Same as for EESZT which is and can be already used portal. **Technical requirements** Structured document specif other value set to be used) **Operational requirements** Only the already existing EESZT is needed. **Ethics requirements** Medical data has to be sent healthcare encounters anc healthcare provision provide

X-Bubble Major Challenges	Developments in EESZT and HIS necessary for structured document handling.
Architecture	

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Ongoing experimentations

X-bubbles

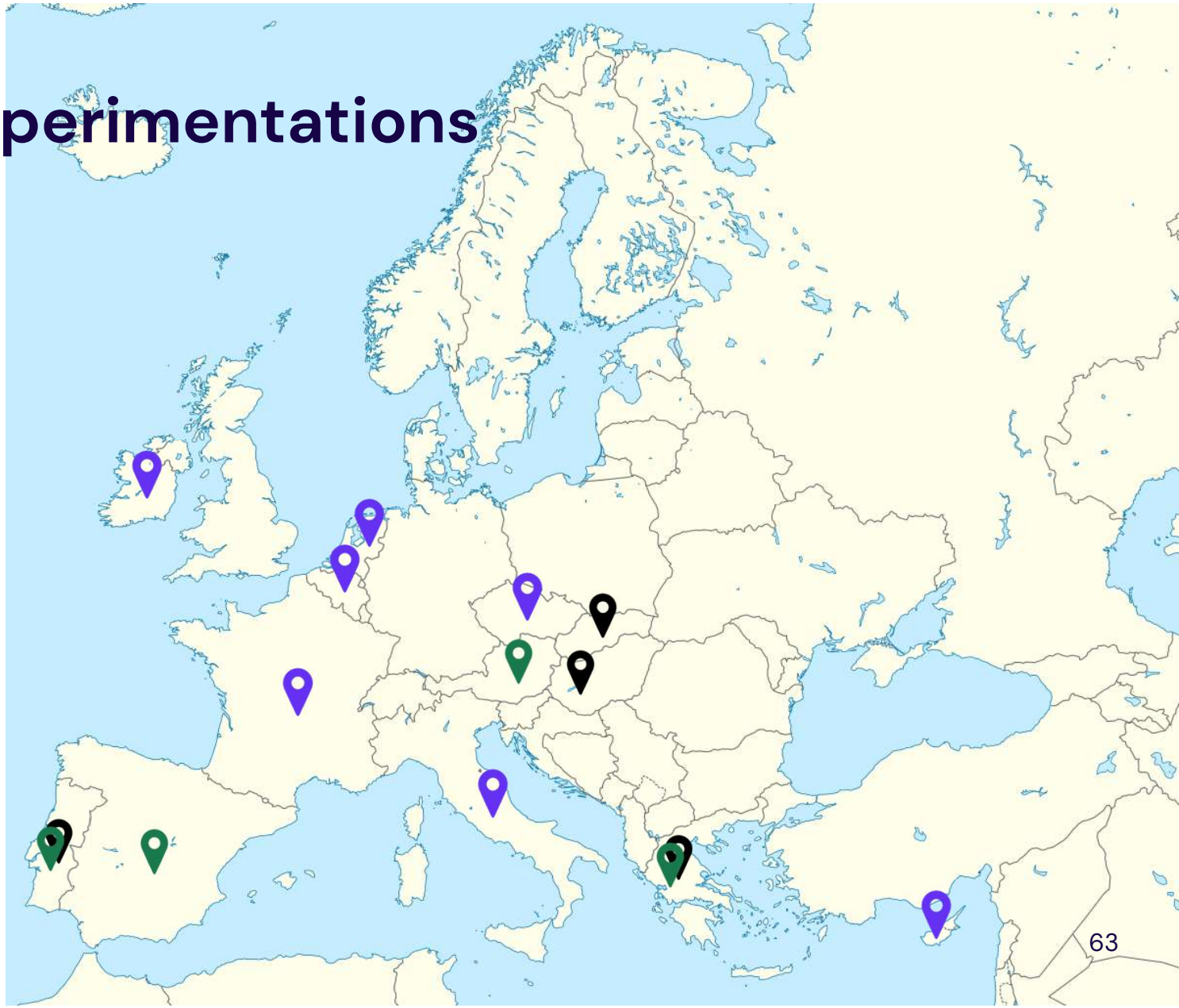
Hungary
Portugal
Slovakia
Greece

“in silico” bubbles

Portugal
Spain
Greece
Austria

Other experimentations

Belgium
Czech Republic
Netherlands
Cyprus
Italy
France
Ireland



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Where we are:

- Laboratory Reports
  - eHealth Network guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - Laboratory Results - https://health.ec.europa.eu/publications/ehn-laboratory-result-guidelines_en.
    - Great alignment with the guidelines, with no missing fields identified.
    - LOINC and SNOMED CT widely used / considered for use.
    - Countries with national strategy and their code systems catalogues with mapping for international ones (e.g. Portugal).
    - Countries with data exchange based on unstructured data, with each laboratory using its own coding system.
  - Laboratory Report Survey available: https://ec.europa.eu/eusurvey/runner/XpanDHLabRep

- Patient Summary
  - The majority of the fields exist in the current systems.
  - In many countries the fields are not integrated in a format compliant way.
  - In the ones that is, the approach used is mostly aligned with the IPS.
  - Patient Summary Survey available: https://ec.europa.eu/eusurvey/runner/XpanDHPS

- Discharge Report
  - Similar strategy to be followed - Analysis in initial phase

* LOINC - Logical Observation Identifiers Names and Codes
SNOMED CT - SNOMED Clinical Terms

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Challenges and Barriers

- Understanding of what the EEHRxF is, its goals and benefits
  - Need to implement large scale targeted campaigns emphasizing exchange and why it is needed
  - Need to develop a detailed analysis that allows to clearly understand the associated benefits and implementation hurdles

- Possibility to integrate information about context specific exchange and by this, establish different procedures
  - Need to integrate means that enable the distinction of aims (primary and secondary use), actors, systems, and trigger the necessary adjustments

- Means to facilitate collaboration and engagement of the different stakeholders, especially across EU
  - Need to establish more efficient and effective mechanisms to hear the voices of doctors, nurses, patients/citizens, policy makers, researchers, and IT

- Coping with existing diversity across MS as well as at national/regional levels in what concerns systems, data models, codes, etc
  - Need for concrete (mandatory) specifications that all systems should follow
  - Need for consistent mappings between national/regional and international coding systems.

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Challenges and Barriers

- Dealing with unstructured information that is still used and, in many situations, seen as necessary
  - Need to introduce appropriate data collection methods or interpretation tools to correctly extract data
- The list of LOINC and SNOMED CT code systems for Lab Reports is very extensive
  - Need for an agreement on appropriate subset of value sets would be relevant
- Large list of data fields for Hospital Discharge Reports
  - Need for an agreement an appropriate subset (depending on specialty)

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XpanDH

Readiness model

Jürgen Brandstätter

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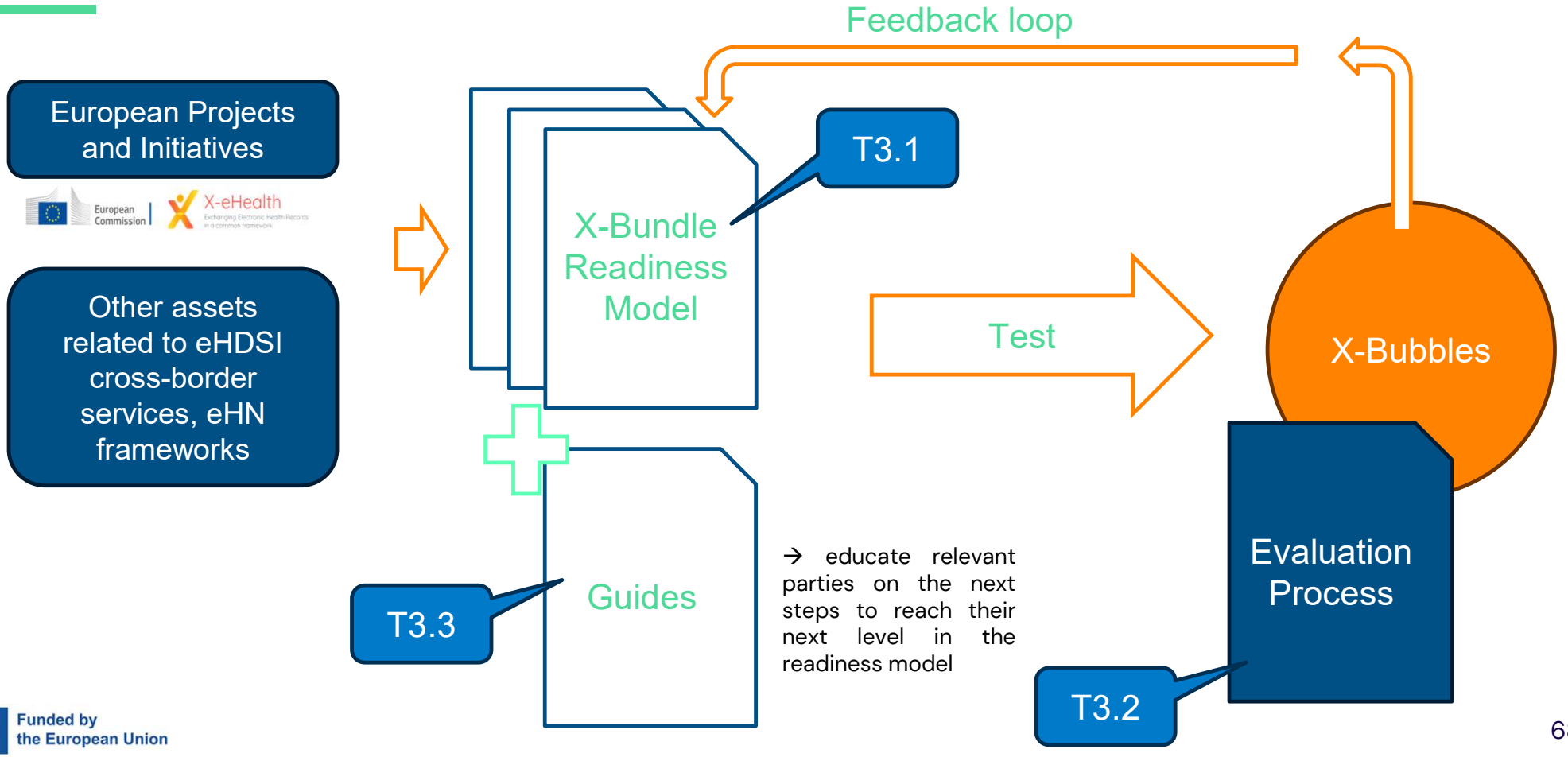
WP3 – Introduction and context



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WP3 – T3.1 Readiness Model

T3.1 will create a Readiness Model to evaluate and guide the IT readiness of healthcare organizations in adopting health information technology (HIT) and electronic health records (EHR)

Lead: IHE Europe
Partners: Iscte, HL7 EU, OKFO, ARIA, CHUP, UNINOVA, ECHAlliance, CEN, ECPC, EDHA

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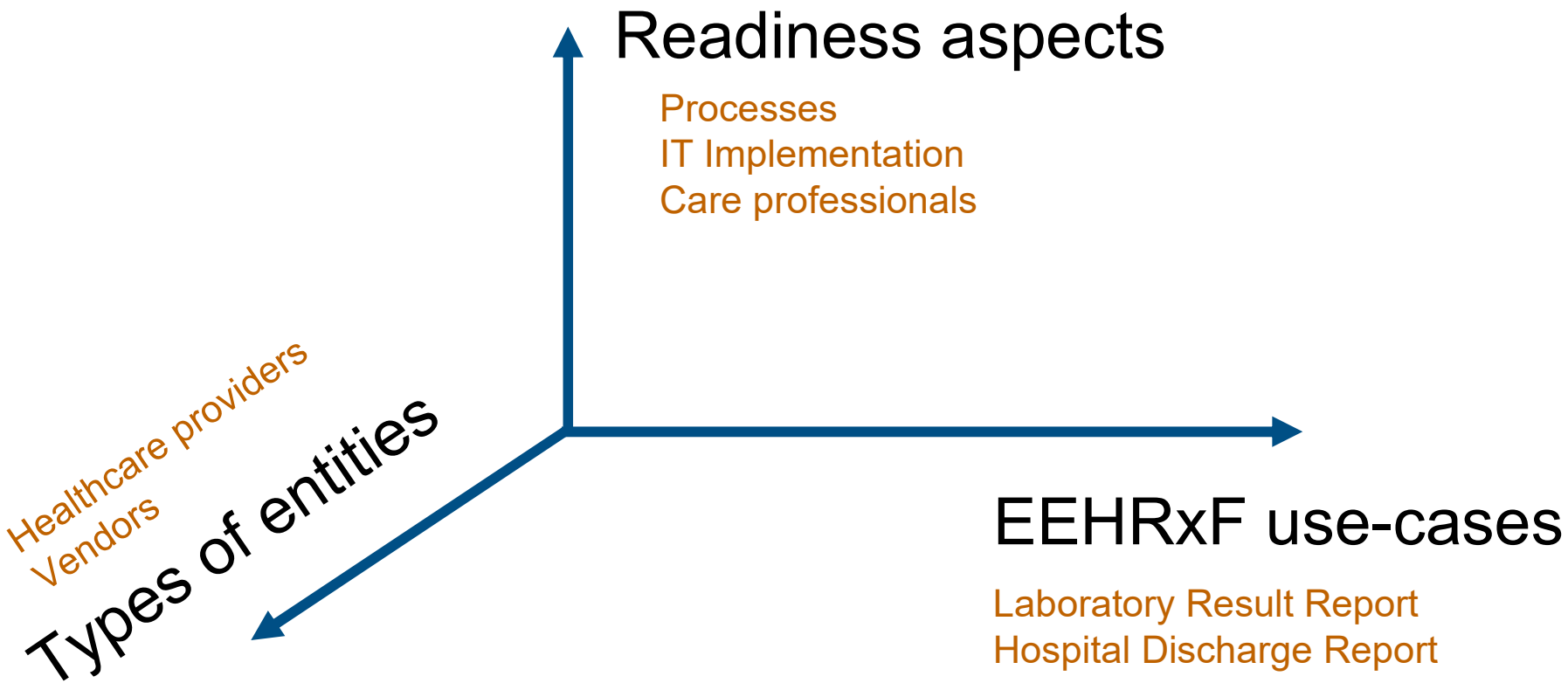
Dimensions of the Readiness Model



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Dimension: “EEHRxF use-cases”

Readiness Model consists of …

- … general parts (use-case independent)
- … use-case specific parts

“Generic” – can be extended by more use-cases

Current use-cases covered:

- Laboratory Result Report
- Hospital Discharge Report

Readiness aspects

EEHRxF use-cases

Laboratory Result Report
Hospital Discharge Report

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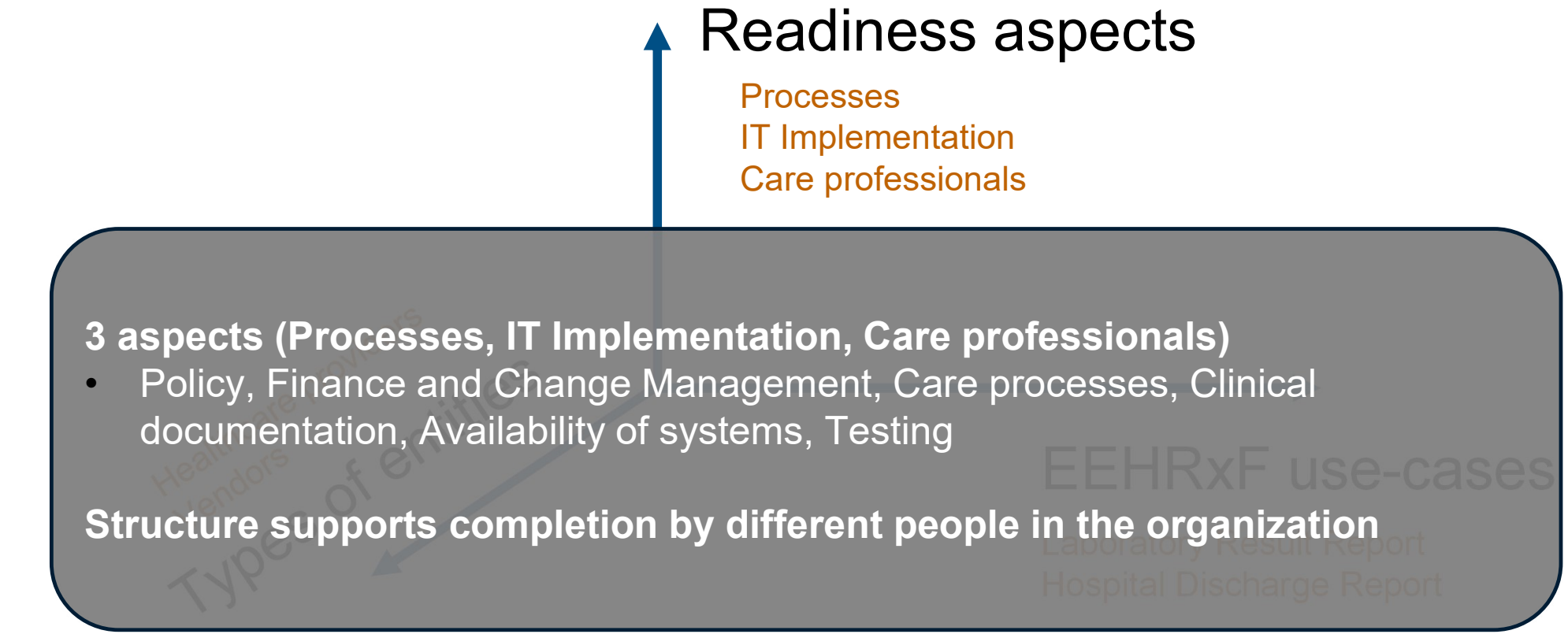
Dimension: “Readiness aspects”



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Dimension: “Type of entities”

Healthcare providers
Vendors

Types of entities

Healthcare providers

- eHealth Agency
- Hospital or Hospital provider
- Daycare clinic
- Community Healthcare provider (General practitioner, Laboratory, Radiology department, …)
- Community Pharmacy
- Nursing home
- Other

Vendors

- Electronic Medical Record (EMR) vendors
- Hospital Information System (HIS) vendors
- Laboratory Information Systems (LIS) vendors
- Other

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Dimension: “Type of entities”

Resulted in 2 Readiness Model surveys

Healthcare providers
Vendors

Types of entities

Healthcare providers

- eHealth Agency
- Hospital or Hospital provider
- Daycare clinic
- Community Healthcare provider (General practitioner, Laboratory, Radiology department, …)
- Community Pharmacy
- Nursing home
- Other

Vendors

- Electronic Medical Record (EMR) vendors
- Hospital Information System (HIS) vendors
- Laboratory Information Systems (LIS) vendors
- Other

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Points to consider for 2024 Summit

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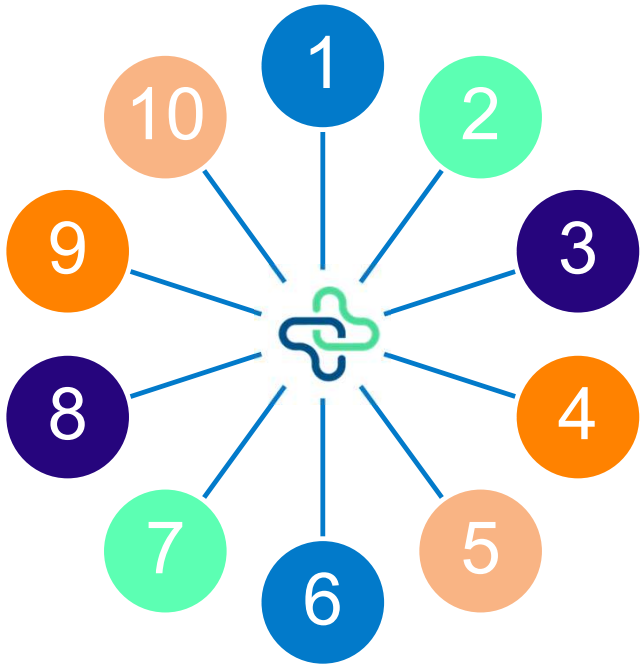
Integration of the ecosystems through the X-nets

X-Nets are networks of organisations directly or indirectly related to health and digital health and that will be involved or need to be involved in an expanding European Digital Health Ecosystem as it matures its use of the European EHRxF (e.g., Networks of Patients and Patient Associations, HCP, ISP, Standards Development Organisations and Industry).



#	X-Net Name
1	Patient Association
2	SDO's & Industry Board
3	Hospitals-on-FHIR
4	Biomedical Research
5	Professionals Associations
6	Citizens and Society
7	Health Mgt & Regulators
8	Innovation Hubs
9	ERN and PerMed
10	Health Regional Authorities

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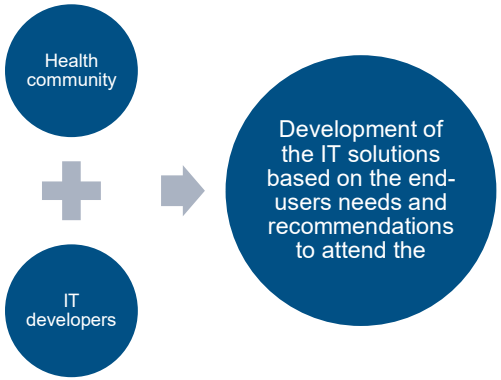
Integration of the ecosystems through Communities

https://xpandh-project.iscte-iul.pt/shape-the-future-of-healthcare-join-xpandhs-community-of-doers-and-co-creators/



The **Community of doers** is bringing together implementers and end-users of new and existing solutions: IT developers and vendors/suppliers on one hand; patients and healthcare professionals on the other, under the concept of the 3C-3P community (Co-creation Community of Patients, Professionals and Programmers). The community is following an open-source community and collaborative approach inviting end-users to participate and support IT developers.

Home » Shape the Future of Healthcare: Join XpanDH's Community of Doers and Co-creators!

Shape the Future of Healthcare: Join XpanDH's Community of Doers and Co-creators!

by / 12/04/2024

What is the Community of Doers?

The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.

How can I contribute?

Participation	Participation is open to individuals from the communities of Patients, Professionals, and Programmers engaged in the healthcare sector.	
Who	Whether representing patients or professionals, working as a programmer for an economic operator, or being involved in academia, start-ups, or innovation, anyone can contribute.	
People, organisations, entities	We seek people, organizations, and entities eager to delve into developing innovative, person-centred concepts that demonstrate the value of **EEHRxF** in practice.	

What's next?

To express your interest in participating in our inaugural Community of Doers and Co-creators webinar on 22 April 2024, 3-4pm CET, kindly click on this LINK. Alternatively, you may reach out to

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Participate through Communities

Community of Doers Page

About the engagement

- We will **work collaboratively** to **identify needs and challenges** and co-create solutions
- Link with the **IT-enabler interoperable solutions**
- Multi-stakeholder **exchange of views** and development of **solutions**
- We **give credit to all inputs** – big or small
- We **welcome people with big ideas, but no time**

We would like to have more Oncologists to identify the needed updates on the current EHR systems and propose upgrades

- **How to onboard?**
  - Assign the form on the CoD page. (QR code)
  - You can also joint us through the Health Professionals X-Nets
- **1st Meeting –**
  - Online workshop - 22 April
- **Next meetings**
  - Workshop in IHE Connectathon (EN) 3-7 June 2024 -> PS, Labs, Discharge rep.
  - Workshop in Madeira (PT) 27 June 2024 -> eP/eD/ePI

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Register to the Community if you haven't done so! Promote the Community

- Register see QR Code
- Our Goals
  - 50 Participants
  - Multiple teams
  - Several countries
- **Teams created will participate in XpanDH Final event in November/December 2024**
- Promote on Social media
  - #XpanDHHealthFuture #CommOfDoers #EEHRxF #EHDS

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XpanDH

XpanDH Foresight:

The Global EHR… why and how

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the European Union

Why and how on Global EHR?

- A global electronic health record (G-EHR) is achievable with focus, concrete steps, value creation and determination to explore certain elements.
- To reach a truly global digital healthcare system, however, we need to work much more profoundly and more decisively on real worldwide cross-border eHealth services, like a global ePrescription system or sharing of minimum sets of data (e.g. the ISO International Patient Summary) and progressively bigger components, such as a vaccination passport, summary or e-cards. For example, medical devices (e.g. insulin infusion pumps, or non-invasive home ventilators) are increasingly globally produced and standardised, yet, the information that they require and generate seems to get ‘chained’ to local, regional or national health systems, in turn, chaining citizens down to their institutions, often their homes. People fear to travel to a remote location where access to their device or health data is not possible. They know healthcare may not be equally safe, which makes them feel unsafe to travel and ‘chained’.
- Digital Health Diplomacy refers to the concentrated international efforts towards supranational interoperability in eHealth/Digital Health. These may include international agreements for mutual health data transmission, recognition of information systems or common approaches to the use of international standards.

What is the Global EHR?

- A global electronic health record (G-EHR) is **a set of interconnected digital systems and services that support the sharing of personal health data across the globe** to support primary use of health data regardless of geographical, jurisdictional and language barriers creating an electronic health record support environment as similar as possible to that experienced by the individual and his/her caregivers in is home country. It is based on standards and is a de facto promotion of data harmonization leading up to a potential "Global Health Data Space" of nominal/anonymized health data for it potential secondary and tertiary use.
- A global electronic health record (G-EHR) is not something utopic. It requires focus, concrete steps, value creation and determination to explore the following elements.
  1) Creating a worldwide voluntary patient and health professionals' registries
  2) Setting up a global regime/governance forum for the advancement of agreements and common creations
  3) Using a common exchange format (possibly inspired in the European EHR exchange format?)
- Source: H. Martins 2020: https://healthmanagement.org/c/healthmanagement/issuearticle/digital-health-diplomacy-in-chained-globalised-health-context

Worldwide eHealth cross-border services

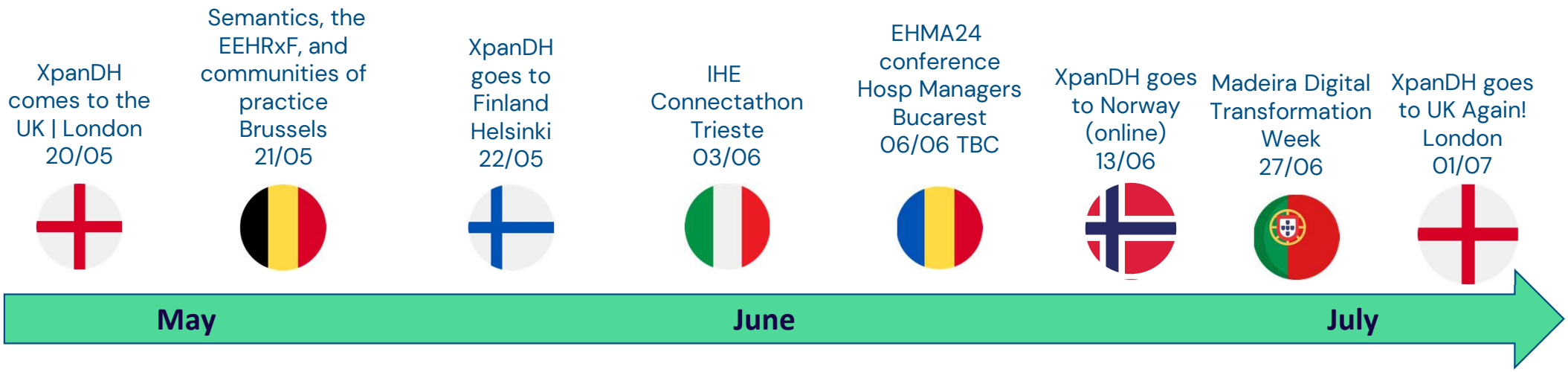
The following worldwide eHealth cross-border services serve as initial steps:

1) Global ePrescription system
2) Global sharing of minimum sets of data (for example, the ISO International Patient Summary) and, progressively, bigger components, such as vaccination passports/summary/e-cards
3) exploring Globally with the EU European EHRxFormat
4) Internationally approved minimum information sets for advanced data-rich medical devices
5) Internationally approved and maintained digital information leaflets for prescribed drugs.
6) International sharing of larges datasets for research/public health based on Commonly agreed minimum sets of data

Global Treaty on Digital Health

Next steps - Xpanding the ecosystem

- **Engagement F2F meetings (set of Webinars – announced in our webpage)**
  - These series of meetings are a core part of the project to ensure the ecosystem Xpansion



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Thanks!

Follow us in our social media.

XpanDH website & Social media

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Agenda

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9/24	12.45 – 13.15	**Plan for internasjonale standarder** *Ingvar Sørlien (Helsedirektoratet)*	Drøfting
10/24	13.15 – 14.00	**Helse-NIM for kritisk info – prosess fremover** *Mari Svardal (Helsedirektoratet)*	Drøfting

Helsedirektoratet

Plan for internasjonale standarder

Ingvar Sørlien og Kerstin E - Helsedirektoratet

Nettside:
Oversikt over arbeid med internasjonale e-helsestandarder

https://www.ehelse.no/oversikt-over-arbeid-med-internasjonale-e-helsestandarder

Hva legger vi i «Internasjonale standarder»?

Standarder for digital samhandling om helseinformasjon

Hovedhensikten er å oppnå semantisk samhandlingsevne (interoperabilitet)

European Commission

EHDS – EEHRxF

IHE INTERNATIONAL Making Healthcare Interoperable

CEN ISO

HL7 International

DICOM Digital Imaging and Communications in Medicine

World Health Organization

SNOMED International Leading healthcare terminology, worldwide

GS1

OMG Object Management Group

LOINC

openEHR

Med flere!

Hvorfor plan for internasjonale standarder?

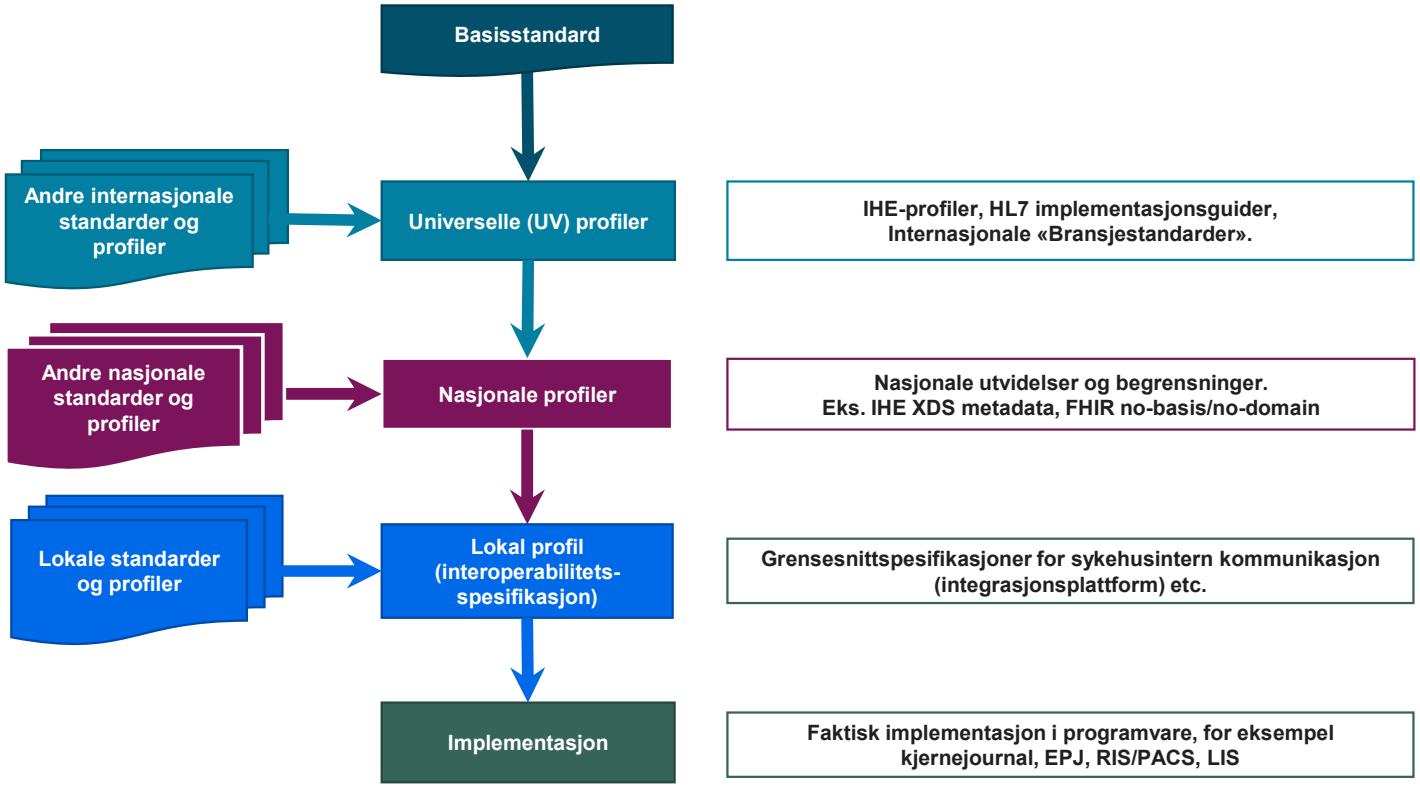
Skape økt framdrift prosjekter i Norge ved å øke gjenbruk av internasjonale erfaringer

Redusere framtidig tekniske gjeld ved å:

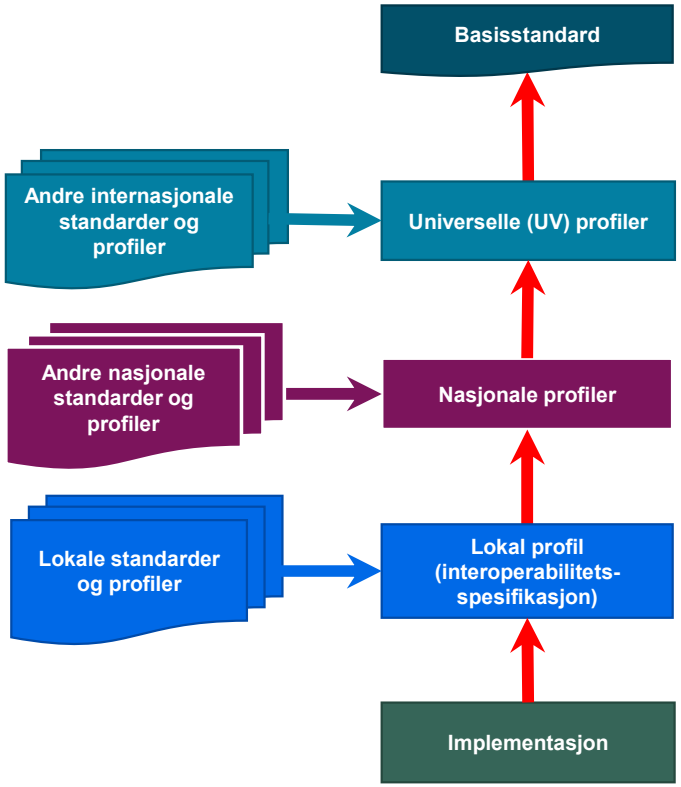
- Påvirke utformingen av internasjonale standarder mot det vi har
- Få eksisterende løsninger til å tilnærme seg internasjonale standarder

Bidra til å se sammenheng mellom de ulike standardiseringstiltak fra myndigheter og helsesektoren

Modell for internasjonal standardisering



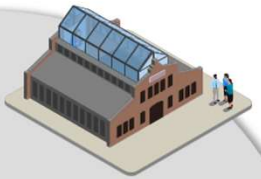
Modell for internasjonal standardisering



Samarbeidsmodellen

- *Bestilling og kvalitetskontroll*
- *Brukerinvolvering*
- *Erfaringsdeling*
- *Bidra til utvikling*

Virksomheter



Leverandører

- *Oversette behov*
- *Foreslå standarder*
- *Erfaringsdeling*
- *Bidra til utvikling*

Innbyggere og helse-personell

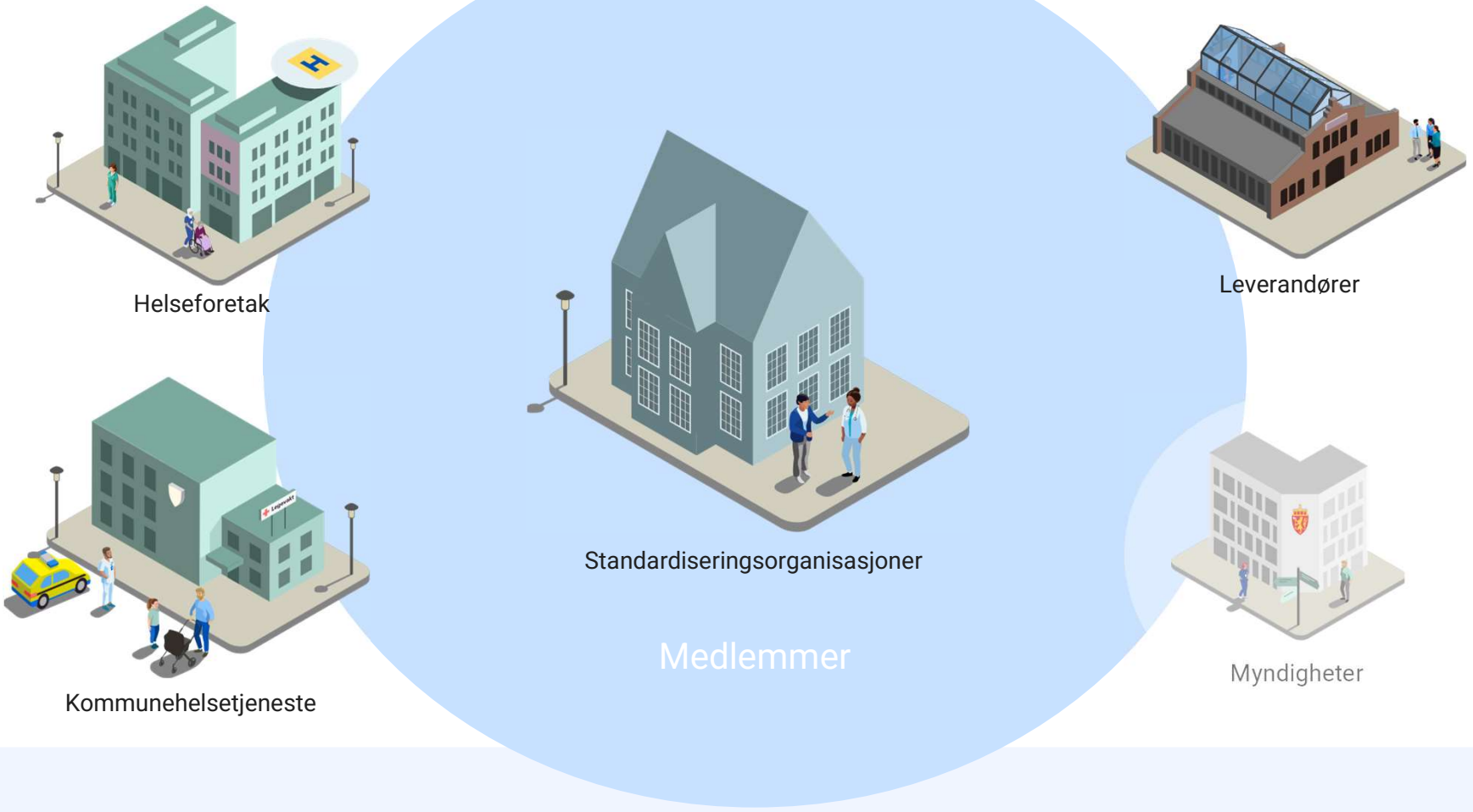
- *Lov og forskrift*
- *Normering og veiledning*
- *Nasjonal koordinering*
- *EU-forordning og samarbeid*

Myndigheter

Standardiserings-organisasjoner

- *Utvikling*
- *Publisering og forvaltning*
- *Kompetansebygging*
- *Rådgivning*

Standardiseringsorganisasjoner



Modell for internasjonal standardisering

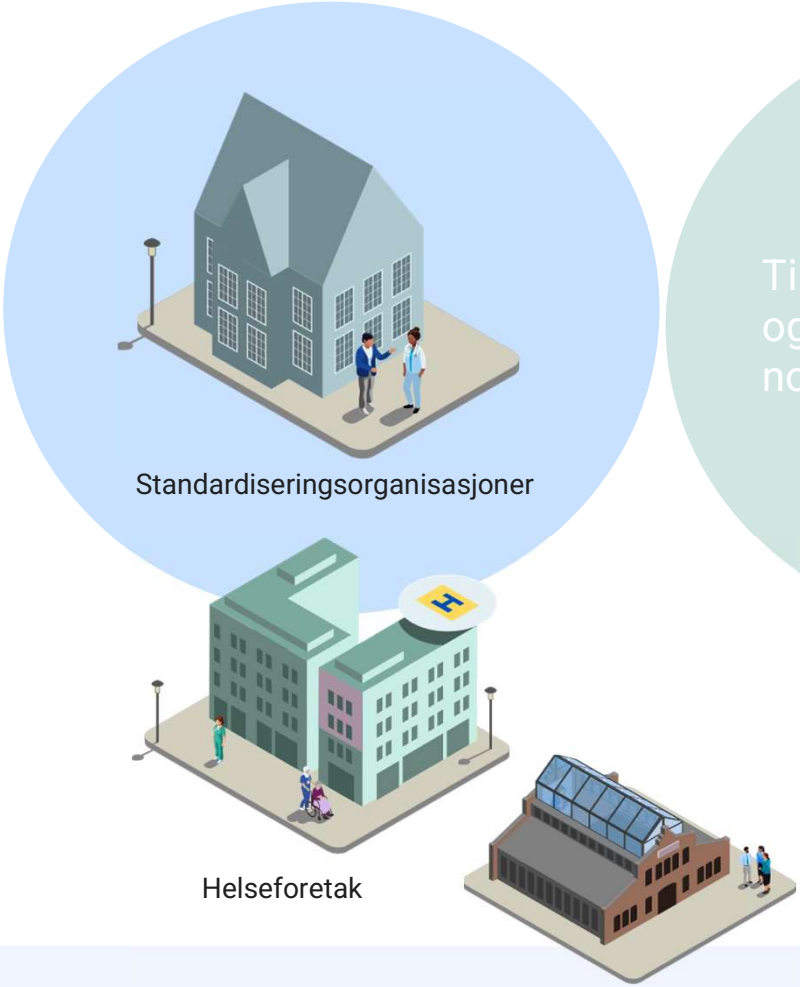
Basisstandard

Universelle (UV) profiler

Nasjonale profiler

Lokal profil (interoperabilitets-spesifikasjon)

Implementasjon



Videre prosess

Innhold i «Plan for internasjonale standarder»

En grovkornet tidslinje som illustrerer ambisjoner:
- EHDS tidsrammer
- Norske ambisjoner for interoperabilitet

IKKE EN DETALJERT PROSJEKTPLAN!

Prosesser og tiltak for å realisere veikartet

Helse-NIM
- Informasjons-modeller med internasjonal retning
- Kunnskapsgrunnlag og GAP-analyser

Xt-EHR
- EU myndighets-samarbeid for å forberede EHDS

HTO
- Standardiserings-koordinator
- xx

XX
- XX

Samarbeidsmodellen

Helsedirektoratet

European Health Data Space

EHDS - Krav til primærbruk, tidslinje og implementing acts

Hva og hvem er EHDS for?

Innbyggere:
tilgang og kontroll over egne helsedata

Bedre diagnostikk og behandling, øke pasientsikkerhet og kontinuitet, få en mer sømløs helsetjeneste

Helsepersonell: enkel tilgang til pasientens helsedata

Beslutningstakere: informerte beslutninger og effektiv styring

Industri: Innovasjon, nye teknologier, behandlinger og løsninger

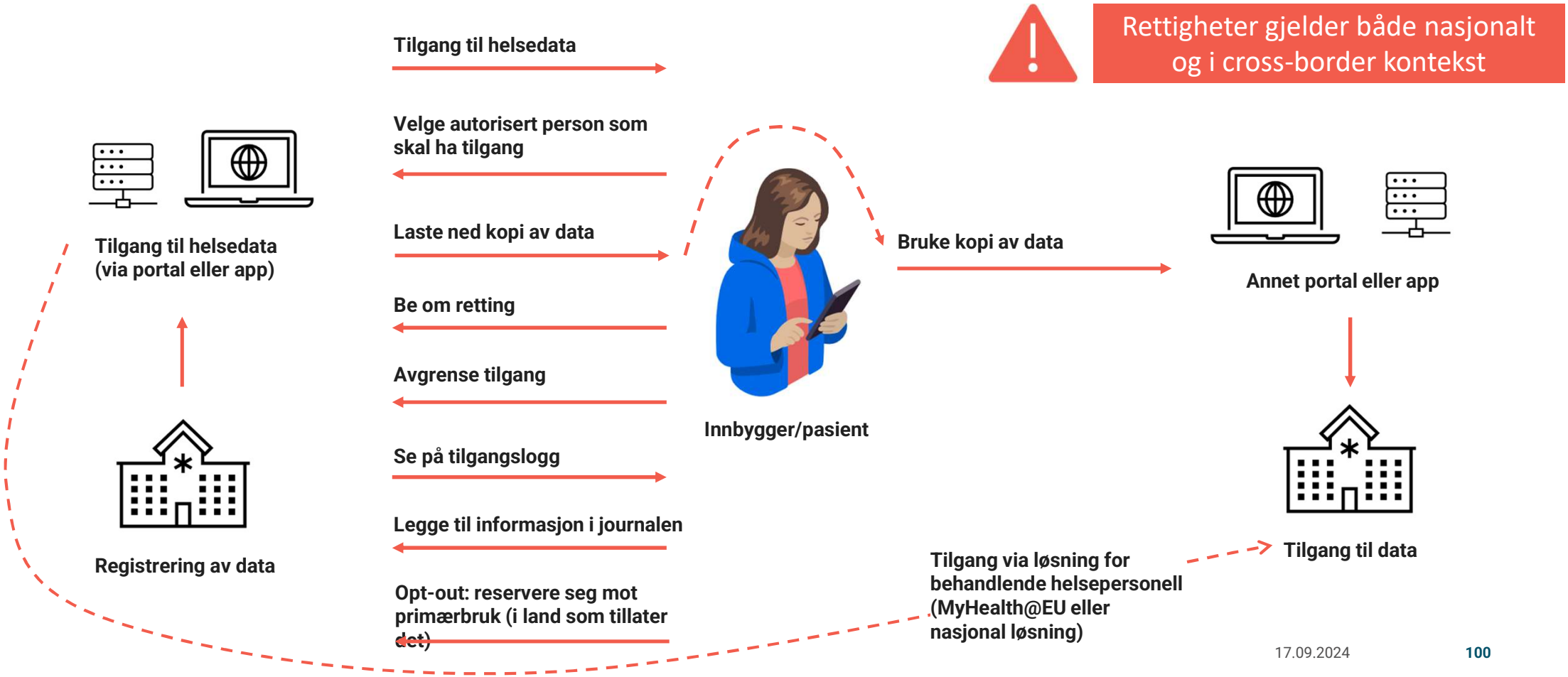
Forskning: Tilgang til helsedata

Bedre helsepolitikk, bedre forutsetninger for forskning og innovasjon

Overordnede mål for primærbruk

- ✓Støtte utveksling av helsedata i helsetjenesten, nasjonalt og på tvers av landegrensene
- ✓Øke datakvalitet og gjøre data mer tilgjengelig for gjenbruk
- ✓Innføre felles, obligatoriske standarder for utveksling av helsedata i hele Europa
- ✓Harmonisering av EPJ-systemer og helseapplikasjoner

Rettigheter til pasienter/innbyggere (primærbruk)



Utvikling av felles europeiske standarder/spesifikasjoner

- **Felles europeisk format =** European Electronic Health Record Exchange Format, EEHRxF, for å utveksle:
  - ePrescription/eDispensation
  - Patient Summary
  - Lab: svarrapport
  - Bildeundersøkelser og -rapporter
  - Epikriser
- **Sertifisering av EPJ-systemer** i EHDS
- **Merking av wellnessapplikasjoner** i EHDS

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

Innovation, experimentation

epSOS, EXPAND, JAseHN, eHAction	X-eHealth	XpanDH	xShare	Further actions
• Development of the MyHealth@EU infrastructure	• Work on lab results, hospital discharge reports, medical imaging • Defined use cases, data sets, data models • Implementation guides for CDA and FHIR	• Further elaboration of the format • Pilots, verification of implementability • Set-up of the ecosystem	• Practical implementation of patient-mediated workflow for data portability • Further development of the exchange format (e.g. care plans, telemonitoring)	

Formalisation

Work on the eHealth Network guidelines	Work by MyHealth@EU Solution Provider	**Xt-EHR** (Joint Action 09 under EU4Health WP2022)	Implementing Decisions under the upcoming EHDS
• Use cases, data sets, principles • Adopted by Member States in the eHN	• Implementable specifications, other artefacts • Implementation in OpenNCP for MyHealth@EU • Adopted by Member States in the eHMSEG	• Work on the formalisation of the format • Requirements for the certification of EHR systems **(recommendations for possible future implementing acts under 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	Original Clinical Documents	Lab results, hospital discharge reports, medical imaging	Further data categories
• HL7 CDA for structured content • PDF available (except eDispensation) • IHE XDS profiles for content transmission	• HL7 CDA header, no further structured content • PDF for content representation • IHE XDS profiles for content transmission	• To be based mostly on HL7 FHIR • DICOM for medical imaging studies	• Not defined yet

European Commission

Krav om felles format, EEHRxF

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(1), setting out the European electronic health record exchange format. Such format shall be **commonly used, machine-readable** and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. The format should **support transmission of structured and unstructured health data**. The format shall include the following elements:

(a) **harmonised datasets** containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;

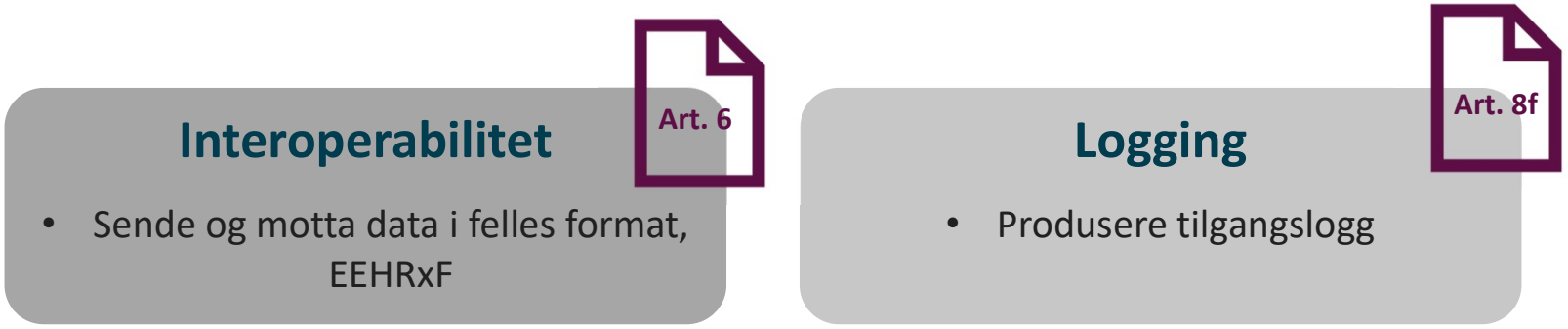
(b) **coding systems and values** to be used in datasets containing electronic health data;

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

3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **issued** in the European electronic health record exchange format referred to in paragraph 1. Where such data are transmitted by automatic means for primary use the **receiving provider shall accept the format of the data and be able to read it.**

EHDS-krav til EPJ-systemer

- Fra 2028/2030 av må systemer ha to harmoniserte komponenter (art. 13)



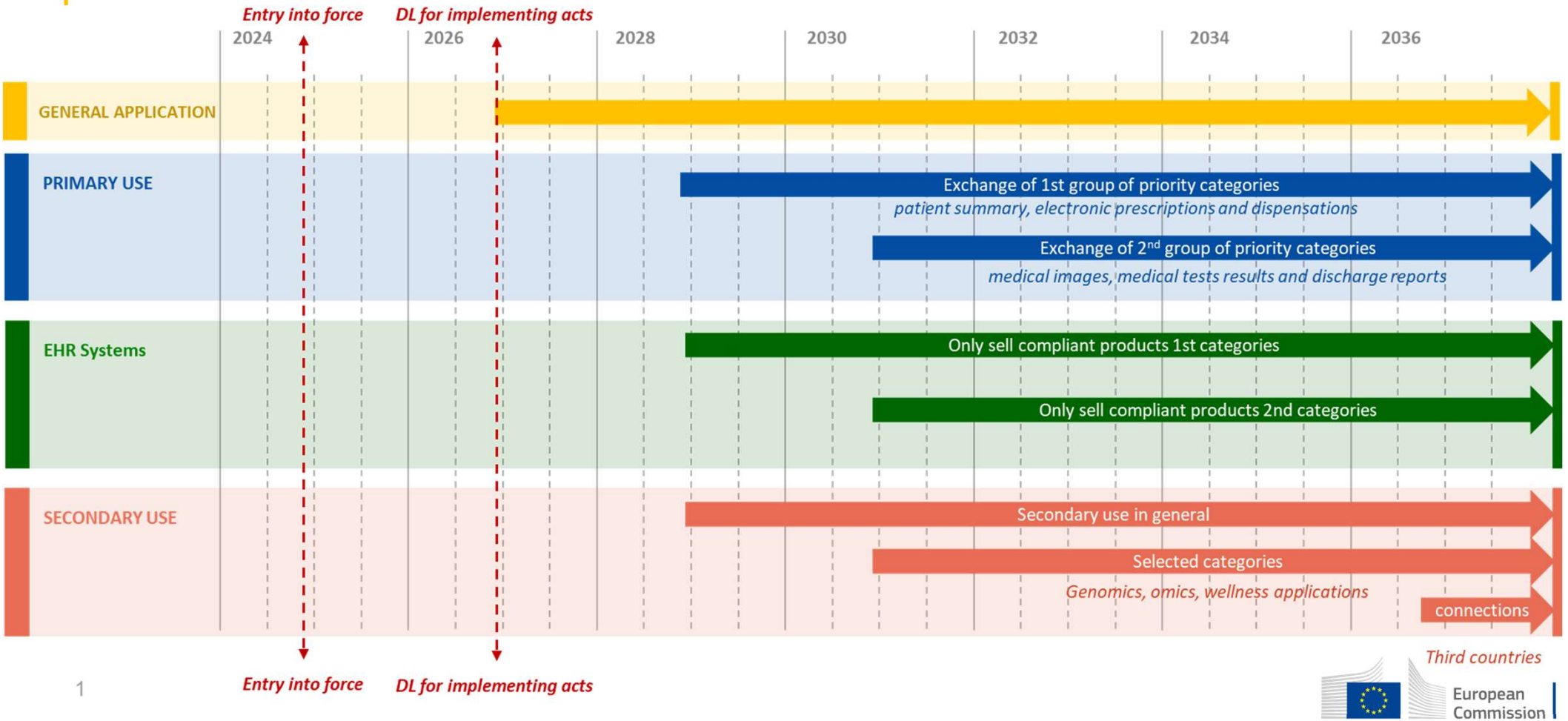
- Land kan sette egne krav knyttet til andre deler av EPJ-systemer - forutsatt at disse ikke hindrer de harmoniserte komponentene
- Krav rettet til leverandører av EPJ-systemer (art. 17): systemene må være konform med spesifikasjonene beskrevet i (art. 23)

Article 31 - Labelling of wellness applications

- Merking av wellness applikasjoner som hevder interoperabilitet med EPJ-systemer

- Label skal inneholde informasjon om:
  - Kategorier helsedata og krav til disse som appen er i samsvar med
  - Referanse til felles spesifikasjoner for å vise samsvar
  - Gyldighetsperiode

EHDS – Overall timeline



European Commission

Xt-EHR leveranser knyttet til implementing acts

	Description
D5.1	Technical Requirements for EHRs and key system interfaces
D5.4	Technical requirements for EEHRxF metadata
D6.1	Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems
D6.2	Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems
D7.1	Laboratory results and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems
D7.2	Medical images and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems
D7.3	Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems
D8.1	Classification and functional profiles of EHR systems guidelines
D8.2	EHR Conformity Assessment Scheme assertion document and checklists
D8.3	Wellness application labelling guidelines

Xt-EHR leveranser knyttet til implementing acts

	Description
D5.1	Techni
D5.4	Techni
D6.1	Patien system
D6.2	Electro requir
D7.1	Labora specifi
D7.2	Medic for EH
D7.3	Discha system
D8.1	Classif
D8.2	EHR C
D8.3	Wellne

Spørsmål / kommentar?

Hvordan skal vi samarbeide frem mot høringene som kommer?

Innspill til september-møte?

Agenda

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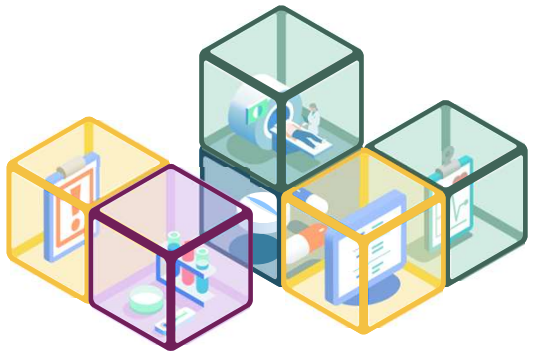
Helsedirektoratet

Helse-NIM

Status for arbeidet med kritisk informasjon

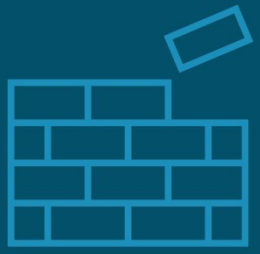
Overfølsomhets-reaksjoner	Smitte	Kritiske medisinske tilstander	Komplikasjoner ved anestesi	Pågående behandling / implantat	Endring i behandlings-rutiner

Standardiseringsutvalget 13. juni 20124
Mari Svardal, avdeling standardisering



Agenda

Hva var Helse-NIM nå igjen?



Hvilke Helse-NIM har vi laga?

Hva skal disse Helse-NIM egentlig brukes til?

Hva skjer videre?

Helsedirektoratet

Hva var Helse-NIM nå igjen?

–

Hva er Helse-NIM?

Hva er en Helse-NIM?

- Helsedirektoratet har et pågående arbeid for å utvikle **overordna nasjonale informasjonsmodeller for helse (Helse-NIM)**
- En Helse-NIM er ganske overordnet, men skal hjelpe til med å se mot det internasjonale, samtidig som vi ivaretar det nasjonale
- Helse-NIM er et verktøy for helsepersonell for å uttrykke kliniske behov
- Skal møte et økende behov i sektor for raskere utvikling av standarder og normerende produkter
- Mål: skape **forutsigbare rammer** og bidra til **innovasjon** og **næringsutvikling**

Hva gjør vi i en Helse-NIM?

- Utarbeider informasjonsmodeller for ulike områder hvor det enten
  - ikke er digitalisert i dag *eller*
  - de digitale løsningene som finnes er ulikt strukturert *eller*
  - det kommer nye internasjonale krav til informasjonen som skal deles
- Finne ut hvilke **informasjonsbehov** som er felles, uavhengig av **hva** informasjonen skal brukes til og i hvilken **kontekst**

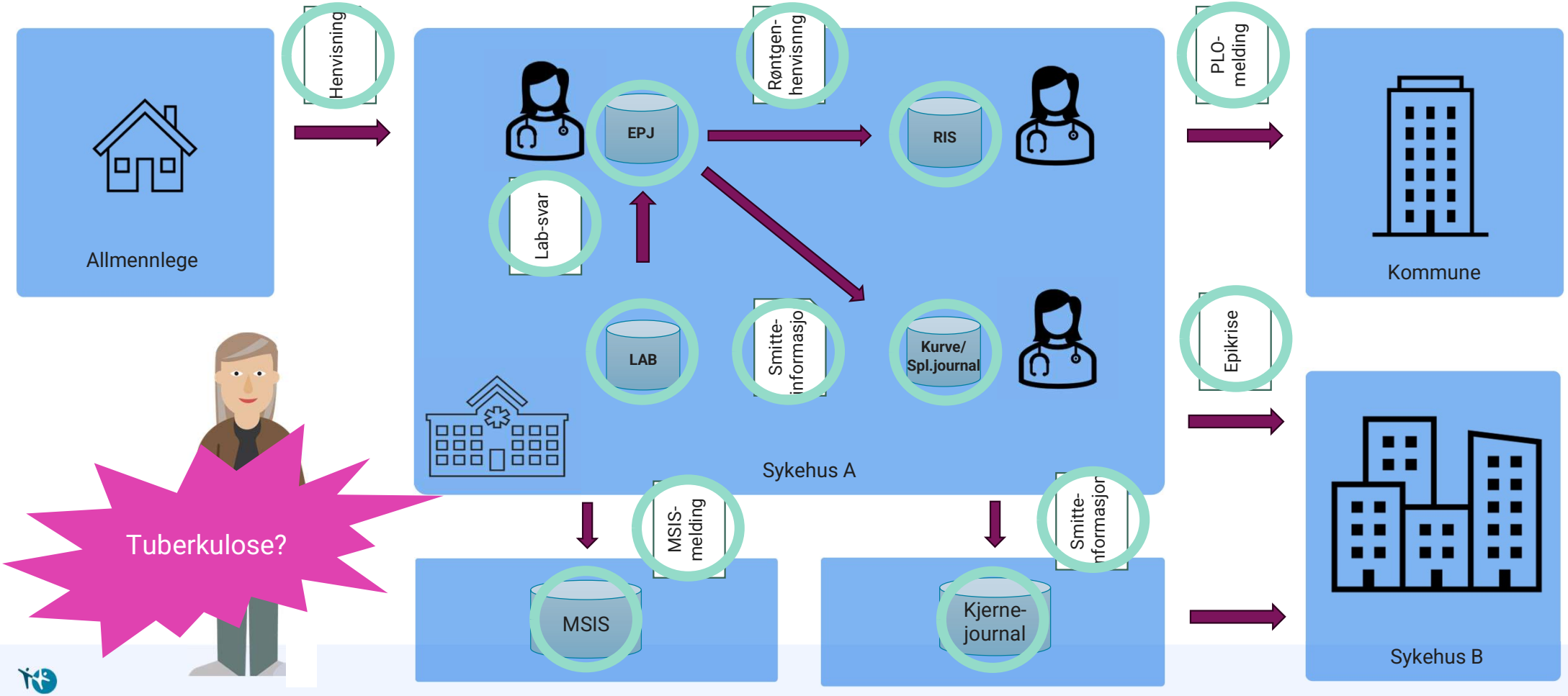
Hvilke Helse-NIM pågår nå?

- Helsekort for gravide
- Røykestatus
- Administrative variabler
- Kritisk informasjon
  - Smitte
  - Kritiske medisinske tilstander
  - Komplikasjoner ved anestesi
  - Pågående behandlinger / implantater
  - Overfølsomhetsreaksjoner
  - Endringer i behandlingsrutiner

I en Helse-NIM ser vi kun på semantikk

- Vi ser på hvilke **informasjonselementer** som er **felles**, og hvilke **definisjoner**, **kodeverk** og / eller **terminologi** som kan dekke **kliniske behov**
- Det vil si at vi **ikke** ser på hva som juridisk, organisatorisk og teknisk må til for å dele informasjon i og mellom virksomheter
- Vi ser **ikke** på hvordan dette teknisk skal implementeres i spesifikke løsninger, som EPJ eller kjernejournal

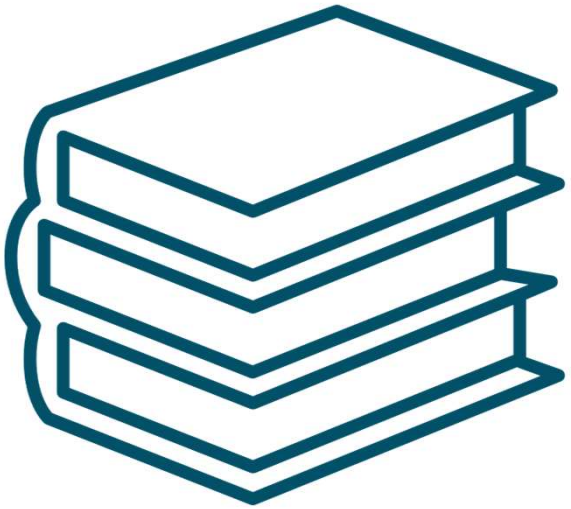
Helse-NIM skal ta hensyn til mange bruksområder



Formålet med møteserien i vår

Utforske hvordan vi kan nærme oss International Patient Summary (IPS) i en norsk kontekst

På bakgrunn av dette - utarbeide overordna informasjonsmodeller for kritisk informasjon



Helse-NIM – føringer og metode

Føringer

- Nasjonal samhandling og kliniske behov er det viktigste
- Legge til rette for internasjonal utveksling (MyHealth@EU)
- Legge til rette for utveksling ved bruk av europeiske formater (EHDS)

Metode

- Vi sammenliknet informasjonsmodellene i ISO IPS, EU PS Guidelines og andre relevante EU-formater med hvordan informasjonen håndteres i norske løsninger (for eksempel EPJ, meldinger, registre)

Resultat

- Forslag til Helse-NIMmer som dekker de obligatoriske feltene fra IPS og EU samt noen viktige felter brukt i norske løsninger

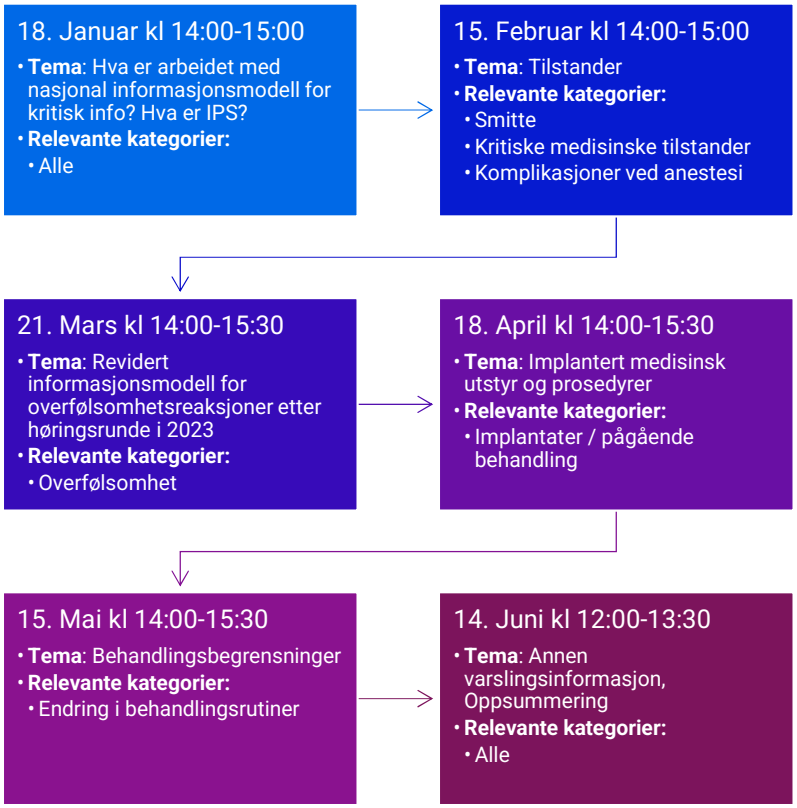
Hvordan har vi jobba med Helse-NIM for kritisk informasjon?

Vi ser informasjonen på tvers av primær- og sekundærbruk

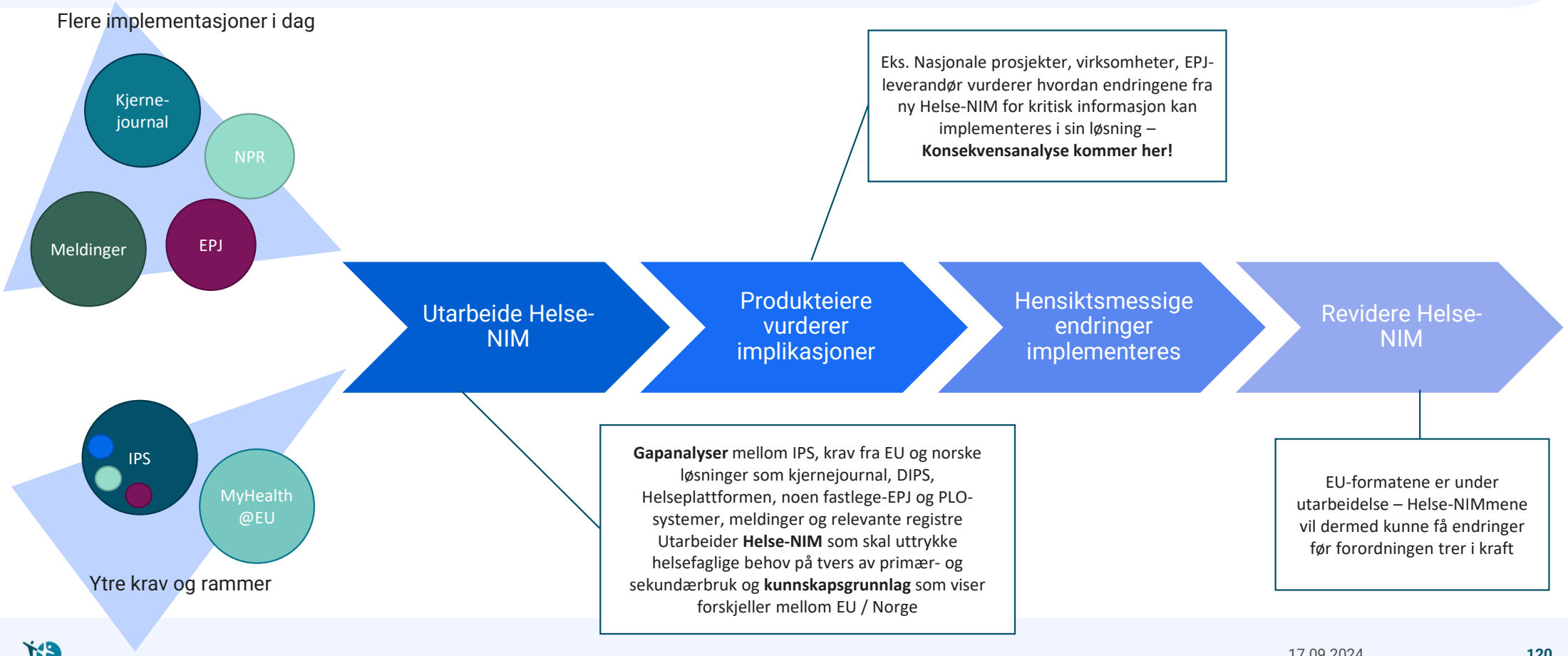
Helsepersonell som viktigste målgruppe

Vi involverer derfor bredt når vi utarbeider en Helse-NIM:

- Mer enn 70 påmeldte til demoene
  - Virksomheter (Helseforetak, kommuner)
  - Leverandører
  - Interesseorganisasjoner
  - Standardiseringsorganisasjoner
  - Flere etater
  - Relevante registermiljøer
- Høring



Hvordan går vi fram?



Helsedirektoratet

Hvilke Helse-NIMmer har vi laga?

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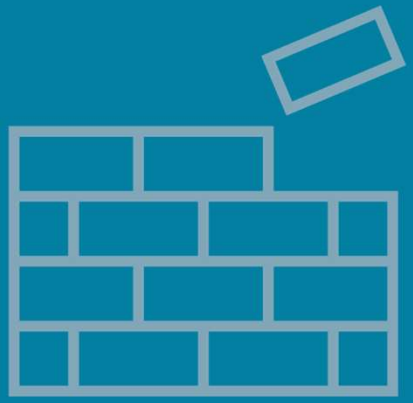
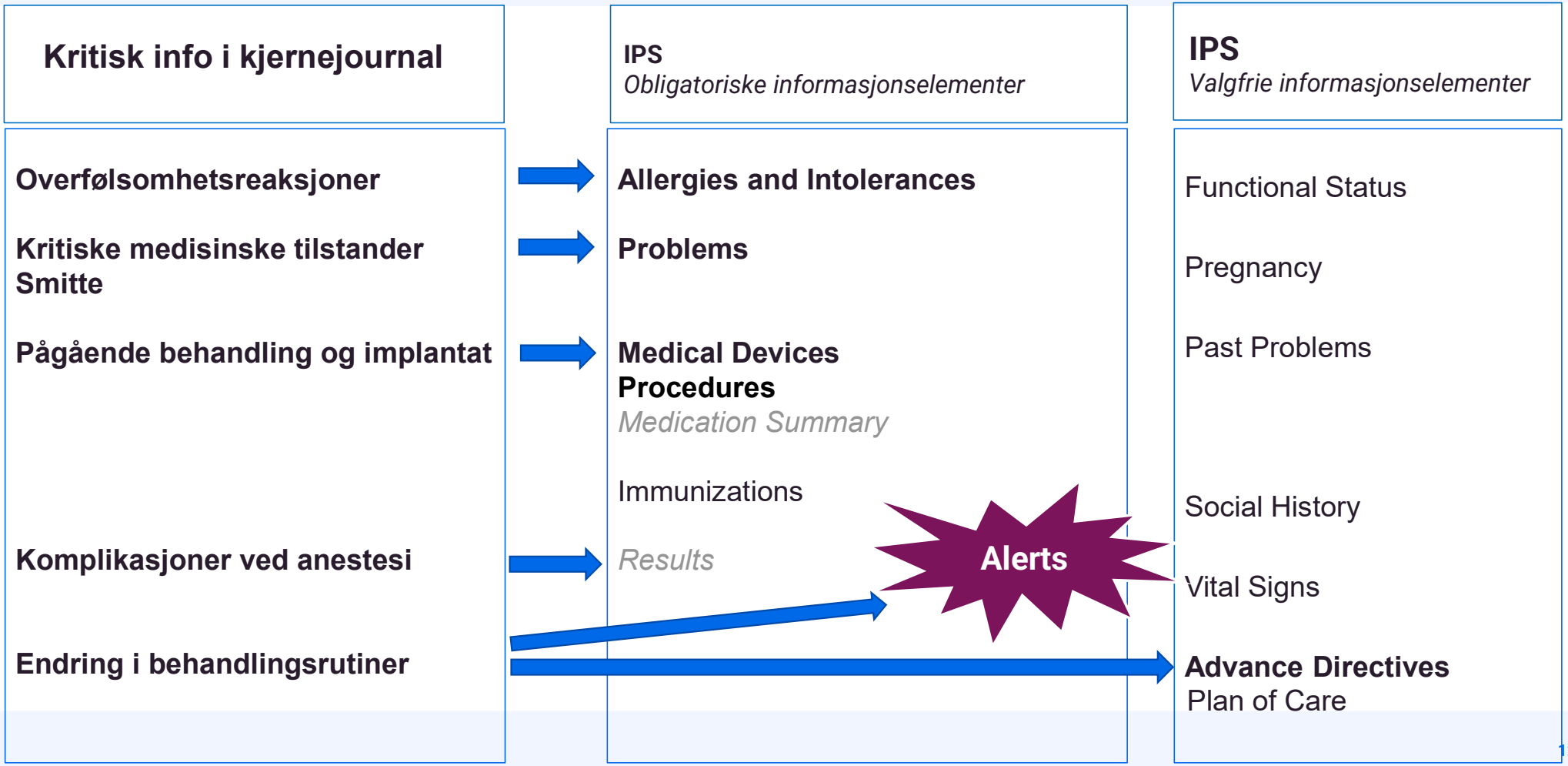


Vi har tatt utgangspunkt i dagens hovedkategorier for kritisk informasjon i kjernejournal



Kritisk informasjon i KJ treffer mange av IPS-kategoriene

Vi har laga følgende Helse-NIM:

Tilstander
- IPS-kategori:
  - Problems
- Kategorier i kjernejournal:
  - Smitte
  - Kritiske medisinske tilstander

Overfølsomhetsreaksjoner
- IPS-kategori:
  - Allergies and intolerances
- Kategorier i kjernejournal:
  - Overfølsomhet

Implantert medisinsk utstyr
- IPS-kategori:
  - Medical devices
- Kategorier i kjernejournal:
  - Pågående behandling / implantater

Prosedyrehistorikk
- IPS-kategori:
  - History of procedures
- Kategorier i kjernejournal:
  - Pågående behandling / implantater

Behandlingsbegrensninger
- IPS-kategori:
  - Advance directives
  - Plan of care
- Kategorier i kjernejournal:
  - Endring i behandlingsrutiner

Varslinger
- IPS-kategori:
  - Alerts
- Kategorier i kjernejournal:
  - Alle

Vi ser behovet for flere for å dekke alle hovedkategoriene

Pågående medisinsk behandling
- Relevant IPS-kategori:
  - Medication summary
- Relevante kategorier i kjernejournal:
  - Pågående behanding / implantater

Resultater / observasjoner
- Relevant IPS-kategori:
  - Results
- Relevante kategorier i kjernejournal:
  - Kritiske medisinske tilstander

Helsedirektoratet

Hva skal disse Helse-NIMmene egentlig brukes til?

–

Helse-NIM har flere formål

Legge grunnlaget bedre samhandling internt i Norge

- Semantisk interoperabilitet internt i Norge gjennom at virksomheter kan bruke Helse-NIM til å strukturere informasjon og kodeverk likt i ulike løsninger, på tvers av primær- og sekundærbruk

Støtte implementering uavhengig av type format

- Helse-NIM er formatuavhengig og skal kunne brukes både for de som skal lage formater for lagring, deling og for registre

Vise retning for kravene fra EHDS

- Ved å se til Helse-NIM når valg skal tas i løsninger / profilering vil leverandører unngå å ta valg som går på tvers av kommende krav i EU-formatene

Spille inn til pågående arbeid i EU

- Xt-EHR-prosjektet med utvikling av formatene – vi spiller inn det vi plukker opp som del av arbeidet (inkl høringssvar)
- Dere kan også spille inn gjennom å delta i standardiseringsorganisasjoner, som HL7 og IHE

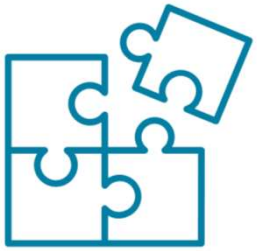
Helsedirektoratet

Hva skjer videre?

-

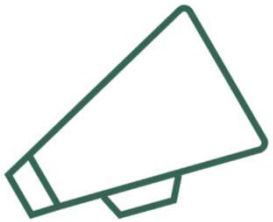
Hva skjer videre nå?

Demoene ferdig



Vi bearbeider innspill

Vi ferdigstiller Helse-NIM-er og kunnskapsgrunnlag



Høring

Helse-NIM-ene skal bidra til å vise hvordan vi kan gå fra det vi har i Norge i dag til det som kommer som krav fra EU gjennom EHDS-forordningen

EHDS-forordningsforslaget vil etter planen godkjennes i løpet av høsten. Det som gjøres nå er hovedsakelig språkvask og oversettelser

Forordningen setter krav til å bruke felles europeiske formater når helseopplysninger utveksles

Formatene må støttes av alle EPJ-systemer ved krav til selvdeklarering for leverandører

Formatene vil være gjeldende fra ulike tidspunkt (tentativt 2028 og 2030)

Områder som skal dekkes av formatene i forordningen er:

- Patient summary (pasientsammendrag) (2028)
- ePrescription (e-resept) (2028)
- Lab results and reports (labsvar- og rapporter) (2030)
- Medical imaging studies and reports (bildeundersøkelser og rapporter) (2030)
- Hospital discharge reports (epikriser) (2030)

Formatene er under utvikling, der Helsedirektoratet deltar i prosessen gjennom EU-prosjektet Xt-EHR

Les mer om arbeidet her: Tilnærming til EU guidelines for utveksling av helsedata – ehelse

Andre aktører kan også bidra gjennom å delta i standardiseringsorganisasjoner, som IHE og HL7

Helse-NIM-ene for kritisk informasjon er basert på det vi vet om disse formatene

Vi spiller inn erfaringer til EU gjennom dette arbeidet. I tillegg vil det bli mer formelle prosesser som er under utarbeidelse

Har dere innspill til hvordan vi kan ta Helse-NIM videre?

Hvordan kan vi involvere på en god måte?

Hvordan kan Helse-NIM være nyttig for dere?

Andre innspill?

Til høsten starter vi opp med ny demoserie for Helse-NIM med temaet:

Legemiddel

Er du interessert i å få invitasjon til dette arbeidet?

Ta kontakt med martha.schei.hynne@helsedir.no

Photo by Hal Gatewood on Unsplash

Møter 2024

- 14. mars, hybrid
- 13.juni, hybrid
- 19.sept, fysisk møte, Oslo
- 5.des, hybrid

Helsedirektoratet