Nictiz

The competence centre for digital information management in healthcare.



How does the Netherlands contribute to the building of the European Health Data Space (EHDS)?

Esther Peelen International advisor/coordinator International Team





European digital strategy

'Fit for the digital age'



Provisionary agreement on the European Health Data Space (EHDS)

Ministerie van Volksgezondheid,

Regulation

Gegevensuitwisseling in de zorg > Actueel > Nieuws >

European Parliament and Council reach deal on European Health Data

and scientific research in the EU. The new law agreed on today will allow patients to access their 66 health data wherever they are in the EU, while also providing scientific research for important reasons of public interest with a wealth of secure data that will greatly benefit the development of health

Frank Vandenbroucke, Belgian Deputy Prime-Minister and Minister of Social Affairs and



Voorlopig politiek akkoord European Health D

en het Europees Parlement hebben van akkoord bereikt over het wetsvoorstel voor gezondheidsgegevens. Dit is een b

pijie.

Dit akkoord dat onder Belgisch voorzitterschap van de Raad is bereikt, ve Frank Vandenbroucke, de Belgische vicepremier en minister van sociale z

pese gezondheidsunie.

Moving forward with the European health data space: the need to restore trust in Jaisalmer de Frutos Lucas a.b.* and Hans Torvald Haugo

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The European institutions reached an agreement on the regulation of European Health Data Space (EHDS) on March 15th, 2024, after three months of intense negotiations that prolonged beyond the original deadline. Harmonizing the needs and priorities of all stakeholders takes time; yet, we critically argue that heated negotiations and fragmentation of the solutions unquestionably shake

In May 2022, the European Commission (EC) presented the EHDS as a framework that would revolutionize European health systems. This space was meant to upgrade the primary use of health data, providing citizens with immediate access to their electronic health records and enabling data sharing with health professionals cross-border. Moreover, the EHDS was set to create a robust legal

Home > Press > Press releases

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

European Health Data Space: Council and Parliament strike deal

This press release was updated on 22 compromise text

The Council of the EU and the Europe agreement on a new law making it eas level. The agreement will now need to

The proposed regulation for a European Health Data Space (EHDS) aims to improve individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes. It provides for a health-specific data environment that

European Health Data Space: Council Parliament strike deal

Data Space: Council and Parliament strike deal





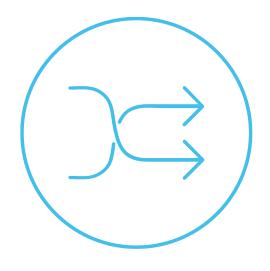
policies.

What does the European Health Data Space envision?



Citizens

Empower individuals to take control of their health data & facilitate exchange of data for delivery of healthcare across EU



Market

Foster a single market for EHR systems



Data availability

For research, innovation, policy, regulation



EHDS has been on a long journey

betreffende de toepazing van de rechten van patiënten bij grenzoverschrijdende gezondheidzzorg Gerien het Verdrag betreffende de werking van de Europeae (5) De gezondheitzszleit van de Unie vormen een centraal onderdeel van het hage niveau van zoolale bescheming van de Urie en diegen hij nez solale zenerhang en zoolale rechtvaarligheid, alzook toe dourrame onevikke-ling Eoventien maken zij deel siet van het bredere kader van dienzien van zigennen belang. Gerien het adviec van het Europeec Economisch en Sociaal Ondrold de nogelijkheien voor patieten om genrove-politijkoole genordheitung ze ontwagen in het lader van deer belijkt, bleven de bitsmere vanstewoeleik, hij het de steel de steel de steel de steel de steel en beweitungt volkende genordheitung aan de hoe-gen op han genogdeien Gowenden mag de ontwiktig van deer richtlijk in underdak wegeving mit de topstring van deer richtlijk in underdak wegeving mit de topstring van deer richtlijk in underdak wegeving mit de topstring van en niet niet dende dat gustenen vorden aasgewoord-digd ook belaten hen liktuur van aanthriting een behan-eleitig in ondergaat. Gezien het adries van het Comité van de Regio's (1). Handelend volgers de gewone wergevingsprocedure (). Overwegende hergeen volgt. Zuels door de Raad in zijn conclusier van 1 en 2 juni 2000 bestelfende de gemeenschappelijke waarden en be-gouden van de gemochtschamist van de Troepas-Unet ty fistens, de onschint van de Raad's vordt en-gemochtschamister in de last Liber voerbegelde. De gemochtschamister in de last Liber voerbegelde Dese gemochtschamisterin de last Liber voerbegelde. Dese sprandedschamisterin de last Liber voerbegelde Dese gemochtschamisterin verzouwen habite in gemochtschapit gemochtschapp, begeen onnotierelijk is om zoerb gemochtschamp, begeen onnotierelijk is om zoerb gemochtschamp. Overenkonutig artikel 183, lid 1, van het Verding be-roffende de werking van de Europeer Lind (VNLS) moet van de Ukse een loog ofvere van bescherning van de maavilike gesondierd worden verscheel. Dit breeken dan de Uks ook waarner zij gemed van ander Ver-denglepelingen handlegen vanzele, een hang vivan van de Verscherning van de maestiele persondierd oner waarborgeningen van de maestiele persondierd oner waarborgening van de maestiele persondierd oner waarborgeningen van de maestiele van de waarborgeningen van de waarborgen van de waarborgeningen van de waarborgeningen van de waarborgen van de waarborgeningen van de waarborgeningen van de waarborgen van de waarborgen van de waarborgen van de waarborgen van de wa on novel patientemobiles de sen hosp situat sus procedución-teming su sarie le lorque, lo di-patido escluring riskonde de Fazid das er prou ventrállen das in de maniento sucuro pas dese susulos no legici-ciales in de liditates gestales usuels gegreen. Me came hecitamo noment in publas sus de proceduciónsis escapa de lorgum recla hobbes en de medicalidora de suculos que partir en la hobbes en de medicalidora de suculos que partir en la hobbes en de medicalidora de suculos que partir en la composição de la partir de de suculos que se a seculos que de la composição de partir de la composição de la composição de la partir de partir de la composição de la composição de la las la composição por la lacida de la composição de la composição de la lacida de lacida de la lacida de lacida de la lacida de lacida de la lacida de lacida de la lacida de lacida de la lacida de lacida de lacida de la lacida de la lacida de lacida (2) Artikel 114, VWTU is de parsende rechtsgrond aangezien het merendeel van de bepalingen van deze richtlijn tot doel heeft de werking van de interne markt en het vrije doel heeft de verting van de interiee mankt en het vrije verlaker van goederen, portunen en destumm es verbeter ven. Omdet aan de voorwaarden voor de toepusing van artikel 114, VWSU als rechnigmond voord voldaan, diest de untide vergevong die rechnigmond is gebruiken zeldt vanneer de leistherming van de volkingenondheid een

2011 Citizens' right on their health data within EU

ou a European Electronic Health Record exchange formet (Terr seich EEA selectore) THE ELECTRICAL CONDUCTION Hering regard to the Treaty on the Ponctioning of the European Union, and in particular Article 292 thereof. The follow of citizens and handboard provident to security access and than determine handle revoids (EMS); that is no are oriented and handboard provident access and the individual provident (EMS); that is no are oriented and handboard and handboard handbo liabiling the secure access and distring of health resource access benieve in the Union will facilizate obtained life in a marker of over-low-feet distriction, such as criticion, and their families, who are converted bridge in another Annales Zone for two jumpouses or resides appoint landing an access converte marker from the beneath the contract the contract of the contract of the contract the contract of the contract the contract of the contract of the contract the contr of directic conditions and a rise in densiond for long-term rate. This is endenoted by bookin spending assessment to 0.0 N of Genero Domester Product in the United on a verbole in 10.17, up from 1.3 N in 1000 ft. Similardy, evidence from various countries reggers that up to 20 N of healthcare spending is writted, for example because patients receive unassessment term or treatments or as a result of revolutible benegitial administration. Digital technologies are powerful colutions to address those inner and to adapt health systems to finance challenges. For example, digital colutions limited to health appet, or wear-she devices, combined with a system that allows a distance secure secure to their own haddle date, through eachile patients with character conditions, noth as

2019 **EeHRxF** Recommendation

Strasbourg, 3.5.2022 COM(2022) 197 final 2022/0140 (COD) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (Text with EEA relevance) (SEC(2022) 196 final) - (SWD(2022) 130 final) - (SWD(2022) 131 final) - (SWD(2022) 132 final)

EHDS Regulation Proposal



2024

EHDS adoption expected



What is the European electronic health record exchange format EEHRxF, 'the format'?

EHDS proposal Article 6:

European electronic health record exchange format

- 1. The Commission shall, by means of **implementing acts**, lay down the **technical specifications** for the **priority categories** of personal electronic health data referred to in Article 5, setting out the European electronic health record mat. The format shall include the following elements:
 - profi The EEHRXF is a set of technical specifications, targeted at see im ontent
 - representation, standards and
- 2. Those imensure that ensuring the interoperability of electronic health record systems and accepted used on the Union market. ... une advisory procedure referred to in Article 68(2). Member States shall electronic health data referred to in Article 5 are provided by a natural person provider by automatic means in the format referred to in paragraph 1, such data shall be read
 - 3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **issued** in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.



For Primary and Secondary use

Primary

- Patient Summary
- ePrescription/eDispensation
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

Via: MyHealth@EU



Secondary

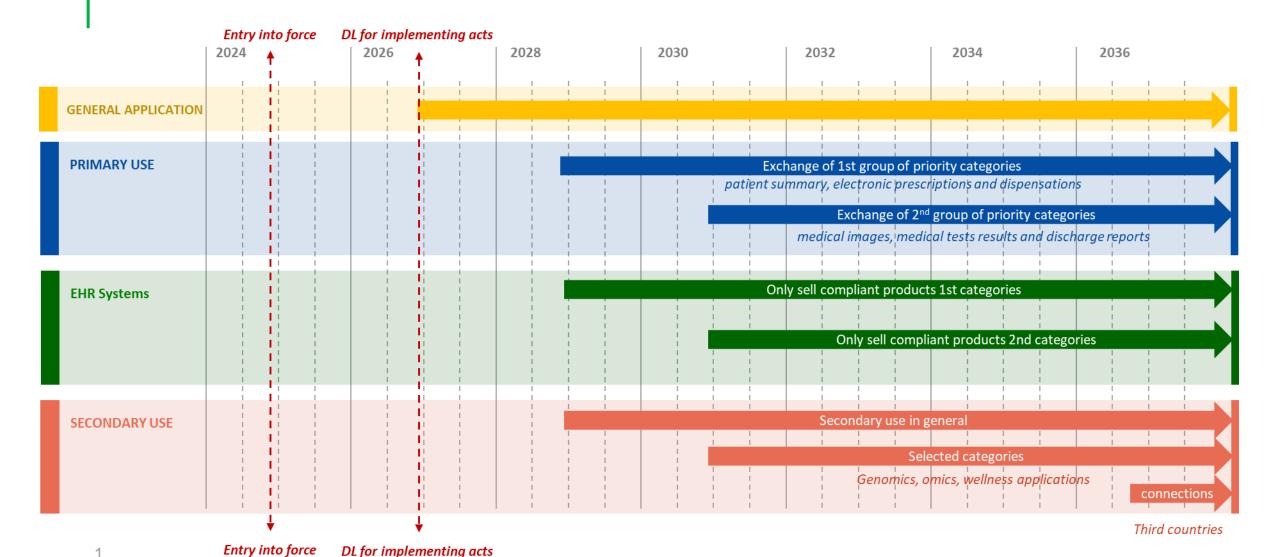
- Research
- Innovation
- Public Health
 - Statistics

Via: HealthData@EU





EHDS – Overall timeline

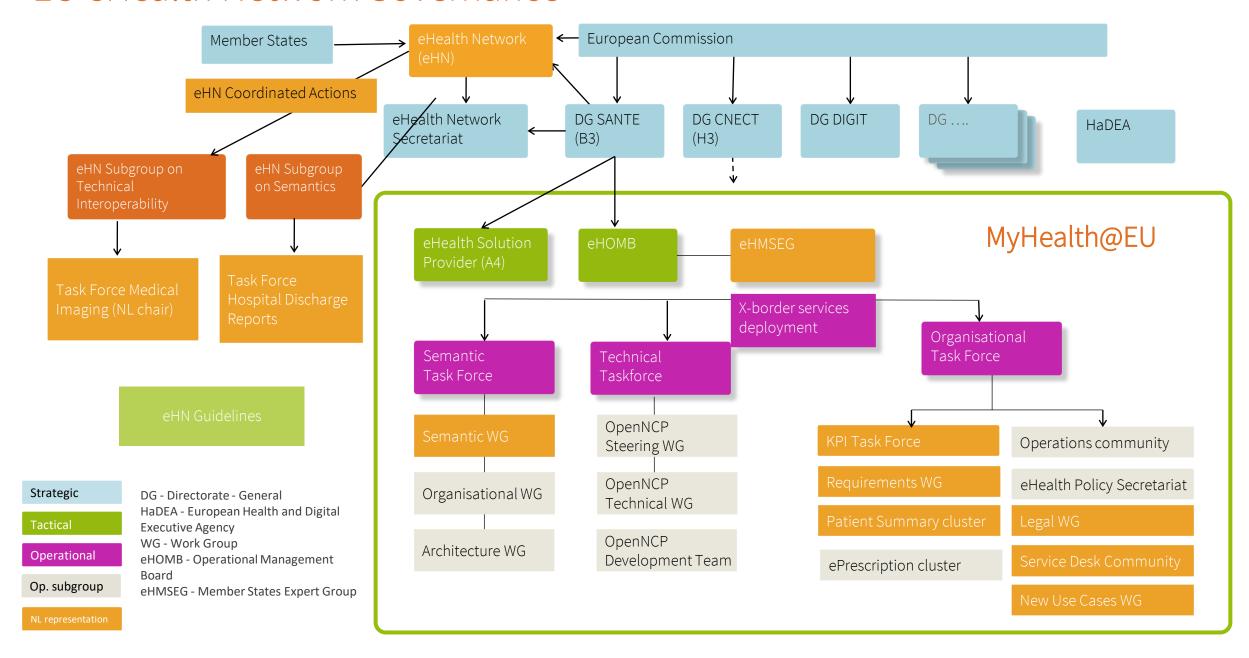




European Cooperation



EU eHealth Network Governance





eHN Guidelines

High level document with descriptions of:

- -Use case (cross-border) and purpose
- -General considerations (legal, policy, international standards)
- -Dataset
- -References

eHealth Network - European Commission (europa.eu)

Are part of the EEHRxF



MyHealth@EU



Infrastructure for primary use of Health Data Via National Contact Points for eHealth In a secure way

Available services:

- European Patient Summary
- ePrescription/eDispensation

New services:

- Laboratory Results
- Medical Imaging & Reports
- Hospital Discharge Reports (HDR)

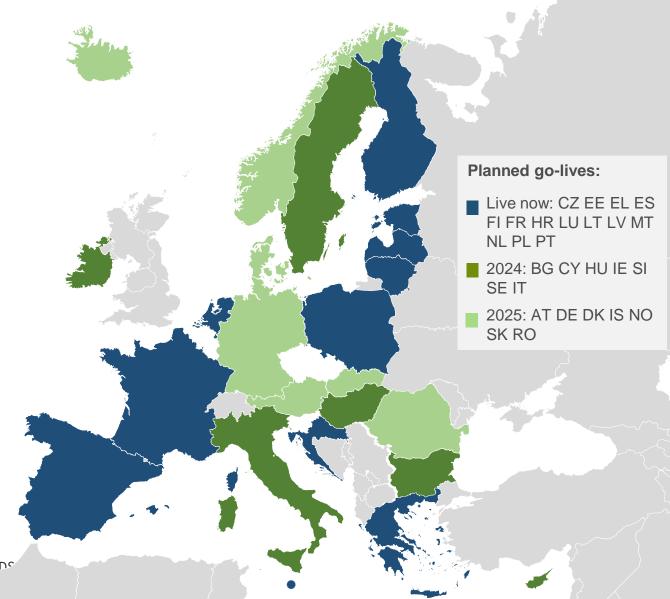
Electronic cross-border health services (europa.eu)



MyHealth@EU: implementation overview

13 Member States are live

Expected grow for EU and EEA countries by 2025





How does the Netherlands participate in the building of the EHDS?





Programme implementation European Healthcare Services: Piezo

Since 2022 NCPeH live in the Netherlands Hosted by CIBG, web portal

Retrieve the European Patient Summary of EU citizens from Czech Republic, Estonia, Portugal, Spain, Malta and Luxembourg.

Listen to the experience of Saxenburg Medical Center (video)

For more information or want to connect? Please contact CIBG



Piezo II – Sharing Patient Summary of Dutch citizen





















Wegiz and EHDS make a strong pair



Wegiz

Dutch Legislation on digital information exchange in Healthcare

Current status

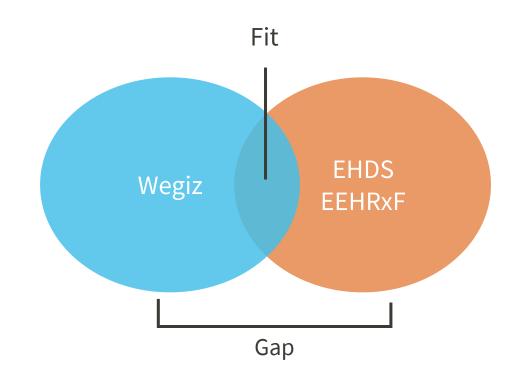


- Proposed Legislation passed Chamber
 (September 22) and Parliament in April 23
- 1 july 2023 into force
- Step-based approach on implementation, spreaded over multiple years (2023-2028)
- Prioritised domains:
 - Patient Summary data
 - Nursing Discharge Report
 - Medical Imaging
 - Medication (prescription and dispensation, medication overview, lab results for medication, adverse event monitoring)
 - Emergency Care

Fit-gap analysis Netherlands/Europe

Wegiz **NL Patient Summary Medication Process** Medical Imaging Nursing Discharge Report **Emergency Care**

EHDS / EEHRxF **EU Patient summary** ePrescription/eDispensation Medical Imaging & Reports Hospital Discharge Letters





Security

Five layer model

Organisation policy Laws & regulations Care process Security Information **Application** IT-infrastructure Healthcare provider A

policy adaption

collaboration

structure & semantics

interfacing

infrastructure

Organisation policy

Care process

Information

Application

IT-infrastructure

Healthcare provider B







Example: Medical Imaging and Reports

Cooperation in eHealth Network subgroup on Interoperability and EU-project Xt-EHR to align National specifications and European specifications

Both sides in development

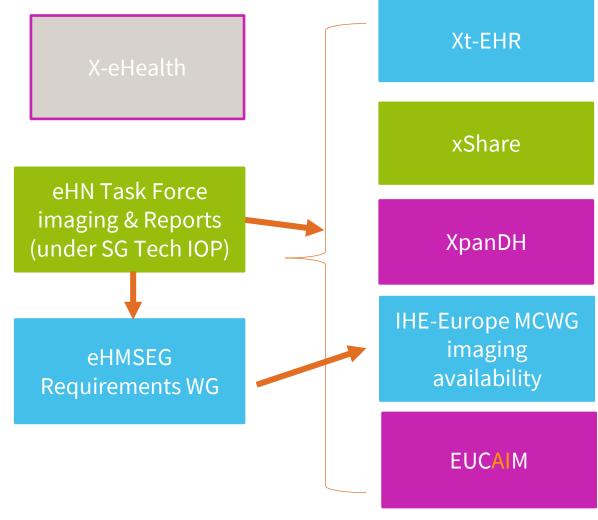
Examples:

Common metadata set

Unique linkage between Imaging study and report Supports Dutch request on building a timeline

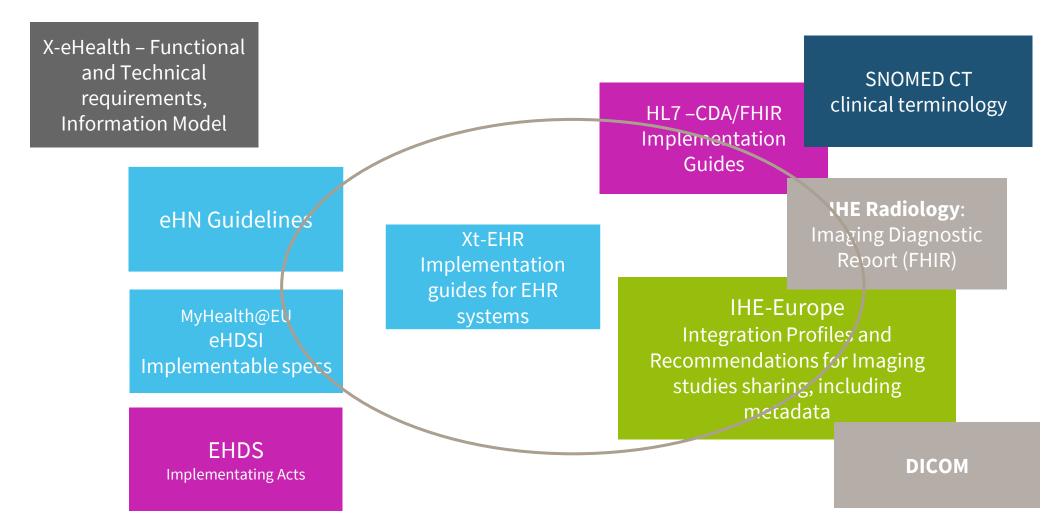


Seeking cooperation in EU initiatives for medical Imaging Studies and Reports under EHDS





Reuse of available material







EU-Projects that facilitate EHDS becoming a reality





Xt-EHR

Project | Xt-EHR

Extended EHR at EU Dataspace for primary use



xShare

<u>xShare</u>



The xShare Yellow Button will allow us to share our health data in the European Electronic Health Records Exchange Format (EHRxF) as noted in the upcoming European Health Data Space (EHDS) regulation.



XpanDH



About the Project Y Communication Y Consortium Y Contact us

XpanDH

Home » News

News

Shape the Future of Healthcare: Join XpanDH's Community of Doers and Cocreators!

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



European EHR **Exchange Format** Summit: Building a Unified European Health Data Ecosystem

The European Electronic Health Record Exchange Format (EEHRxF) Summit, held in December 2023, brought together key stakeholders to discuss the development, challenges, and future of





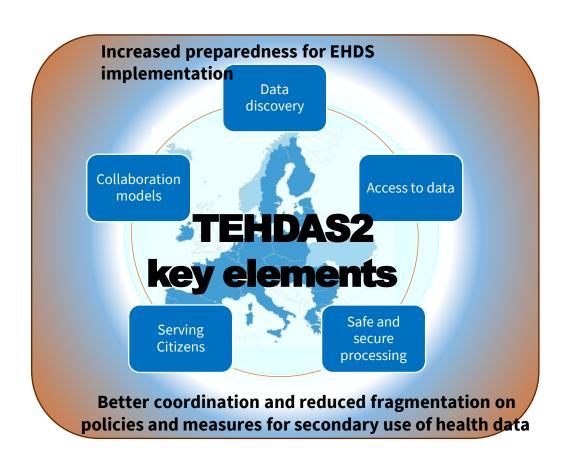


PatheD

Patient Access to eHealth Data







TEHDAS2

Towards the European Health Data Space **TEHDAS** project

1-5-2024 t/m 1-1-2027

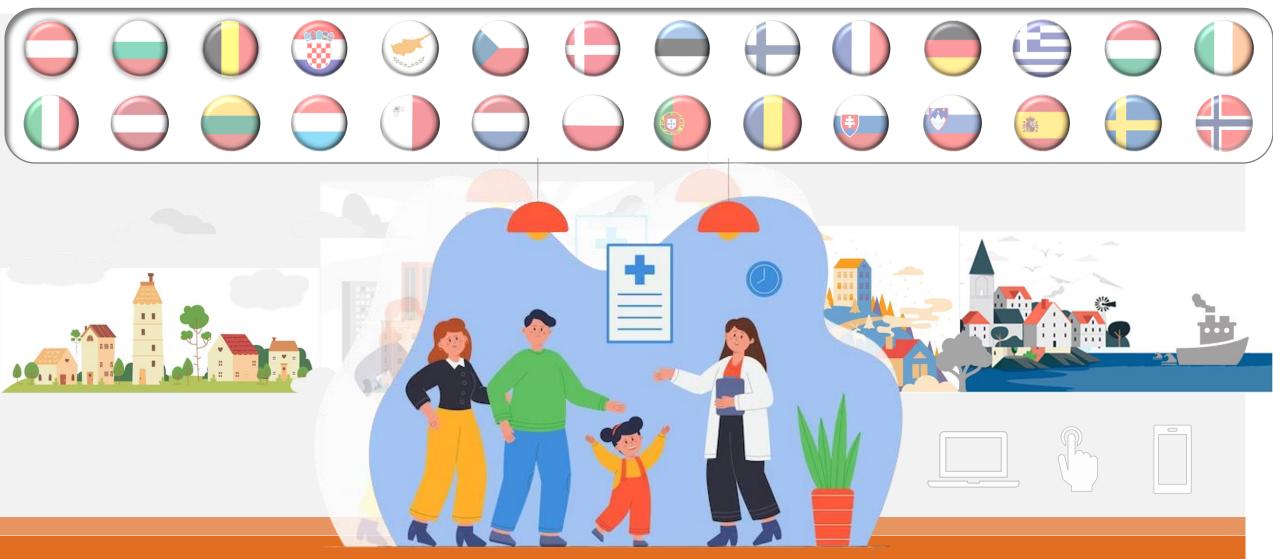






Extended EHR@EU Data Space for Primary Use

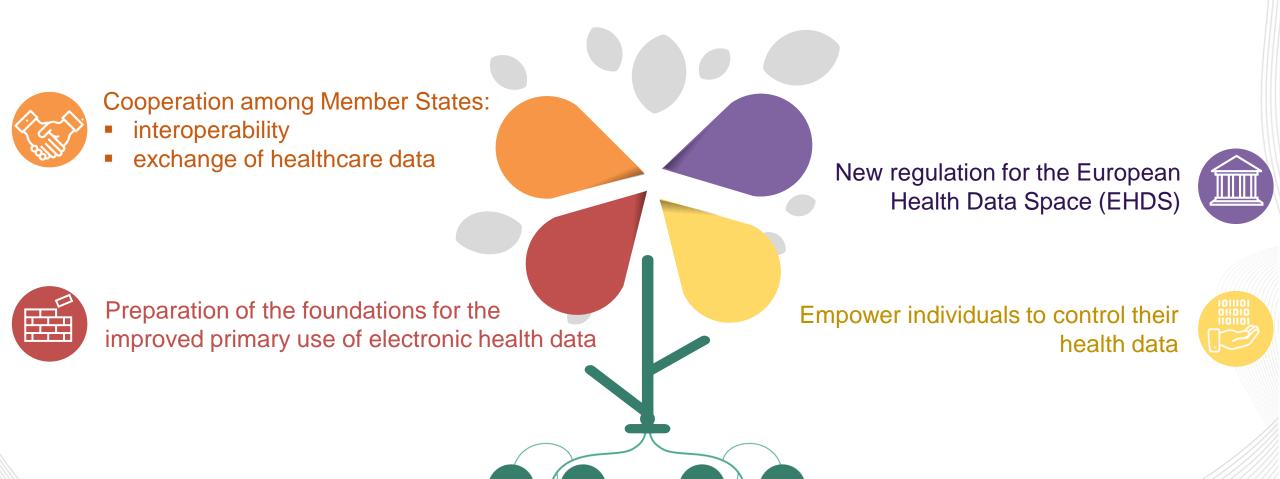




Participants: 28 countries, 55 organisations



Extended EHR@EU Data Space for Primary Use



Purpose

EHR solution in the European Digital Single Market

- Cross-border interoperability
- Technical Specification and Use Cases
- Implementation Guides
- Common agreed on use case





Purpose

Definition of implementation guides for EHRs





EHR-System definition

EHDS, article 2:

'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;



Work Packages





Stakeholder involvement

European level

MedTech Europe (MTE)

Digital Europe (DE)

Standing Committee of European Doctors (CPME)

European Federation of Nurses Associations (EFN)

European Society of Radiology (ECR)

European Patients Forum (EPF)

European Committee for Standardization (CEN)

...and many more





Your input is very welcome!

If you want to get involved, please contact me at Esther.peelen@nictiz.nl



Ambition

Digital Health for all Member States







Future events



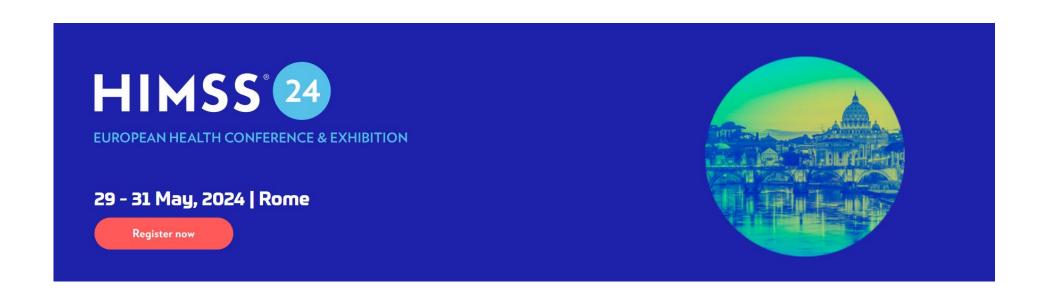
xShare – High Level Interoperability Workshop 21 May



Registration



HIMSS Europe 29-31 May, Rome



Program



IHE-Europe Experience Days 3 and 4 June, Trieste

- Medical Imaging best practices from EU-countries and beyond
- Gemini (IHE/HL7)
- EHDS, Al Act, Interoperability Act

Program & Registration







Questions?





More information

<u>Internationaal – Nictiz</u>

XpanDH Webinars

EEHRxF Recommendation 2019

About NCPeH:

Home | NCPeH-NL

MoH Meet up, this afternoon





Keep in touch!

We'd love to hear your questions, needs and suggestions

