



**SUMMER SCHOOL ProMIS**  
Edizione 3 – Anno 2023

“Le Azioni Congiunte nella Programmazione Europea: strumento chiave per prioritizzare i bisogni, creare capacity building e massimizzare implementazioni e impatti nei sistemi salute regionali”

04-05-06/07/2023 – Mondello (PA)

SPLENDID HOTEL LA TORRE  
Via Piano di Gallo, 11 – Mondello (Palermo)



ProMIS

# Digitale: overview

**Fidelia Cascini**

Assistant Professor of Hygiene and Public Health, Università Cattolica S. Cuore

Digital Health Expert, DGSISS, Ministry of Health



UNIVERSITÀ  
CATTOLICA  
del Sacro Cuore



*Ministero della Salute*

# 2021: IL MONDO È SOPRATTUTTO DIGITALE



## Popolazione totale

7.85 mld

**+81 mln rispetto al 2020**

(urbanizzazione 56.4%)

## User di telefoni cellulari

5.22 mld

**+93 mln rispetto al 2020**

(66.6% della popolazione)

## User di Internet

4.66 mld

**+316 mln rispetto al 2020**

(59.5% della popolazione)

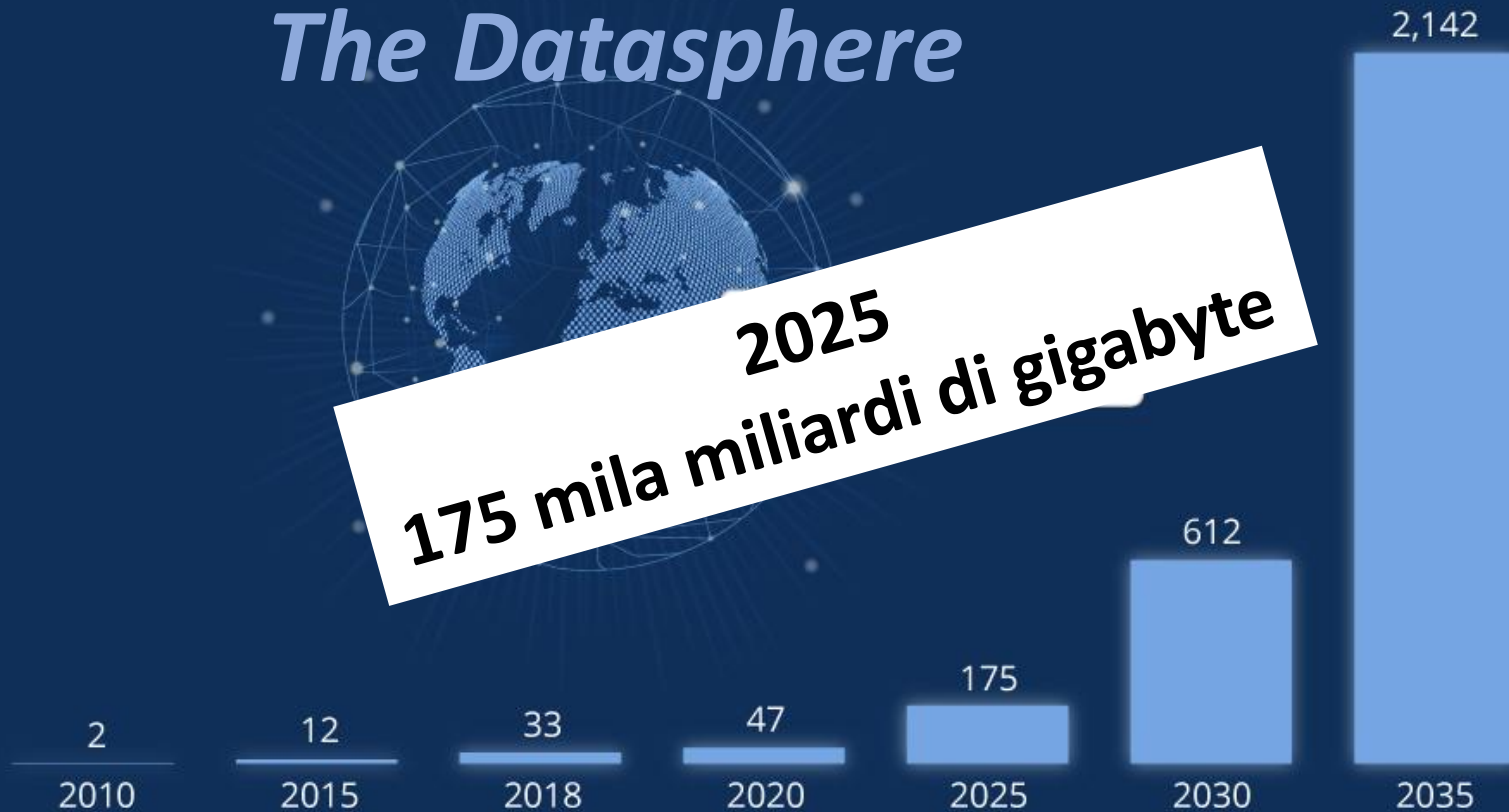
# 2025: IL MONDO SCOPPIA DI DATI DIGITALI

## Global Data Creation is About to Explode

Actual and forecast amount of data created worldwide 2010-2035 (in zettabytes)

### *The Datasphere*

**2025**  
**175 mila miliardi di gigabyte**



In 1 anno  
**270 Gigabyte a persona**  
riguardano dati di **Salute e**  
scienze della vita

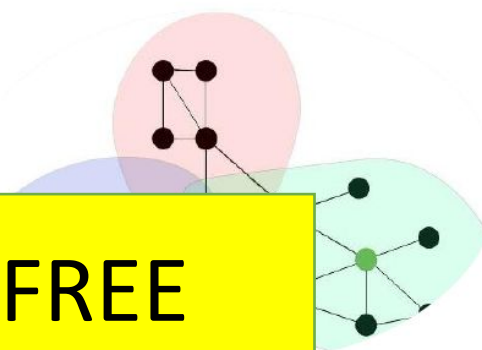


@StatistaCharts

Source: Statista Digital Economy Compass 2019

statista

# European Data Strategy for European data economy



**FREE MOVEMENT OF PERSONAL DATA, FREE  
MOVEMENT OF GOOD AND SERVICES**

## **Cross-sectoral governance framework**

DGA and Data Act

## **Enablers**

Investments in data spaces  
and federated cloud  
infrastructures

## **Competences**

Empowering individuals,  
investing in digital skills &  
data literacy and in  
dedicated capacity building  
for SMEs.

## **Common European data spaces**

in crucial economic sectors and  
domains of public interest,  
looking at data governance and  
practical arrangements.

**HORIZONTAL DATA POLICIES**

# DEFINIZIONE DEI PROBLEMI

- Strumenti limitati e frammentari per il **controllo dei cittadini** sui propri dati sanitari e sulla loro trasmissione digitale, locale e cross-boarding
- Limitata **interoperabilità tecnica e cyber sicurezza** per frammentazione di formati standard, protocolli e requisiti, l'erogazione di prestazioni sanitarie che beneficerebbero della digitalizzazione
- **Riferimenti legislativi, regole e** procedure amministrative divergenti, e infrastrutture frammentate per **l'uso secondario** dei dati
- **Accesso limitato del decisore** politico ai dati sanitari anche quando necessario per fronteggiare un'emergenza sanitaria

# Funding Opportunities for Digital Health in 2021-2027



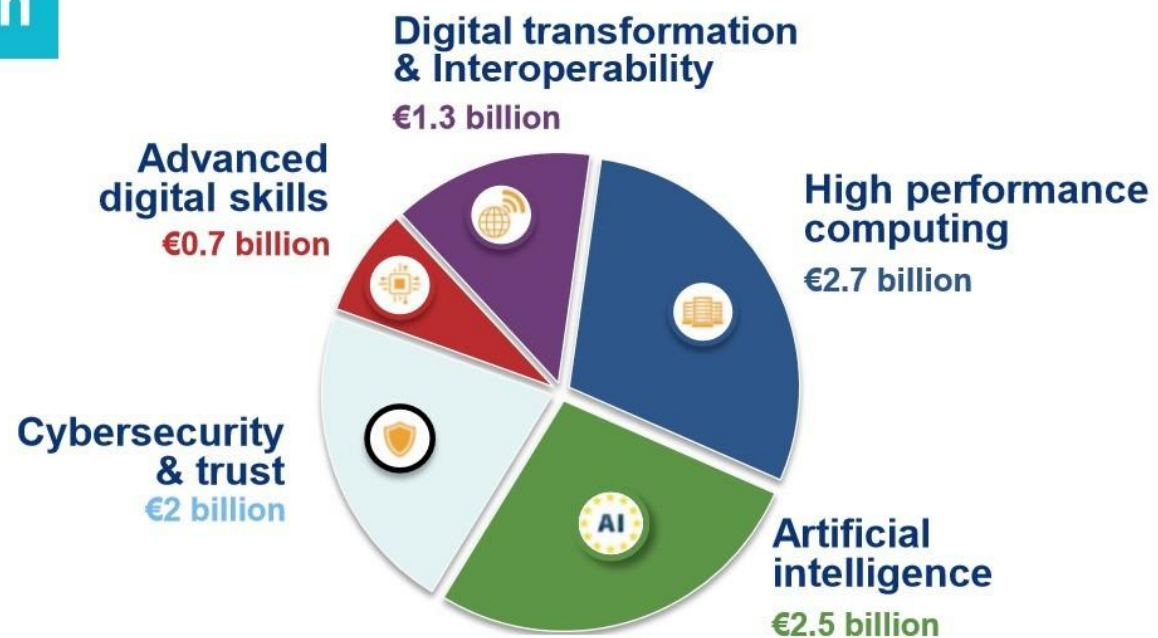
European Commission

## EU4Health programme for a healthier and safer Union

#EUBudget #EU4Health

## Digital Europe Programme

€9.2 billion in total



EU BUDGET FOR THE FUTURE  
HORIZON EUROPE  
#EUBudget #HorizonEU

## European health challenges

- ⌘ Ageing population and chronic diseases putting pressure on health budgets
- ⌘ Unequal quality and access to healthcare services
- ⌘ Shortage of health professionals

## Potential of digital applications and data to improve health

- ✍ Efficient and integrated healthcare systems
- ✍ Personalised health research, diagnosis and treatment
- ✍ Prevention and citizen-centred health services

## What EU citizens expect...

- 90% agree** To access their own health data (requiring interoperable and quality health data)
- 80% agree** To share their health data (if privacy and security are ensured)
- 80% agree** To provide feedback on quality of treatments

## Support European Commission:

### 1 Secure access and exchange of health data



#### Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

#### Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.



Updated 24/04/2018

### 2 Health data pooled for research and personalised medicine



#### Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

#### Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with 'one million genomes by 2022' target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

### 3 Digital tools and data for citizen empowerment and person-centred healthcare



#### Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).



#### Actions:

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.



# 2021: DCC E GATEWAY EUROPEO

**Proof of vaccination**  
for medical purposes





V1-ME-12345678  
ASBCD-56789-44

Name DOE Joe  
Date of Birth 1987-06-05  
Adm. gender Male  
Passport number PF12345678  
National health ID 050687-987F  
Certificate issued 2021-06-02

<b>Dose 1/2</b>	<b>Dose 2/2</b>
Type C19-mRNA	Type C19-mRNA
Date 2021-02-03	Date 2021-02-24
Brand Comirnaty	Brand Comirnaty
MAH Pfizer Oy	MAH Pfizer Oy
Batch AB123CD	Batch EF456GH
Adm. centre Hospital 1	Adm. centre Health centre 2


Country Middle East  
Issued by Name Health service  
Signature District



QR code is the same as  
in "Basic" or "Standard"

ME-telecom

**Proof of vaccination**



Reveal less      Reveal more

**Level:**  
Basic

Name D\*\*\* J\*\*\*  
Date of Birth \*\*8\*.\_\*\_5  
Certificate issued 2021-06-02


**Vaccination**  
Type C19-mRNA  
Date 2021-02-24



"Quick simple check"

ME-telecom

**Proof of vaccination**




Reveal less      Reveal In full (enter PIN)

**Level:**  
Standard

Name Doe Joe  
Date of Birth 1987-06-05  
Adm. gender Male  
Passport number PF12345678  
Certificate issued 2021-06-02

**Dose 2/2**  
Type C19-mRNA  
Date 2021-02-24  
Brand Comirnaty  
MAH Pfizer Oy


▽ Scroll for more?



"Standard check"



ME-telecom

**Proof of vaccination**




Reveal less      Reveal more

**Level:**  
Full details

**Verification details**  
UVC1:  
  
V1-ME-12345678ASBCD-56789-44  
  
HFGT-HETS-POZ3-BS12-ABSC

▽ Scroll for more  
Name Doe Joe  
Date of Birth 1987-06-05  
Adm. gender Male  
Passport number PF12345678  
National health ID 050687-987F



For authorized and authenticated  
verifiers only

Online verification <https://www.npsme.health/c19verify>  
Scan to open verification page: Enter cert ID and verification code:  
HFGT-HETS-POZ3-BS12-ABSC





COMMISSIONE  
EUROPEA

Strasburgo, 3.5.2022  
COM(2022) 197 final

2022/0140 (COD)

Proposta di

**REGOLAMENTO DEL PARLAMENTO EUROPEO E DEL CONSIGLIO**

**sullo spazio europeo dei dati sanitari**

(Testo rilevante ai fini del SEE)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} -  
{SWD(2022) 132 final}

# MAGGIO 2022: LA COM PRESENTA

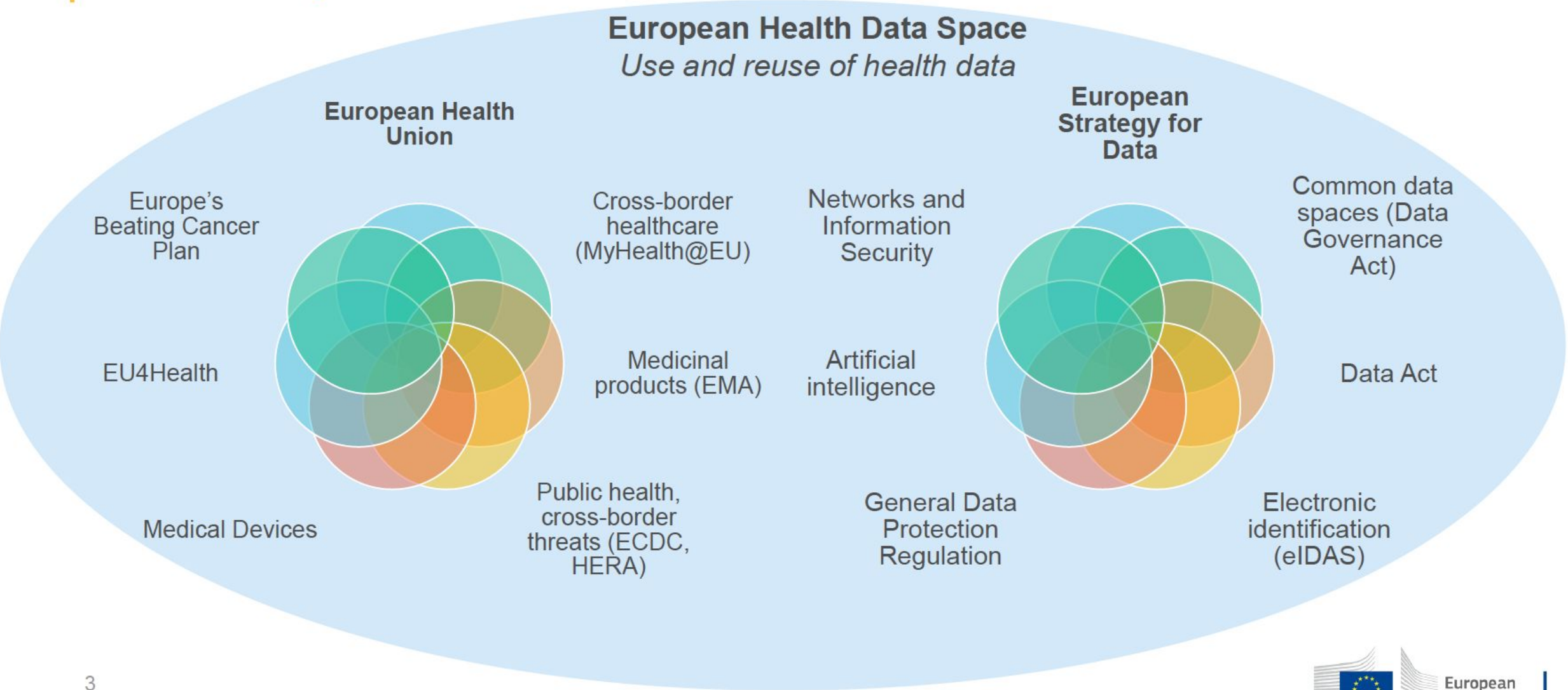
## *European Health Data Space*



—  
**European  
Health Data  
Space**

#EHDS  
#HealthUnion

# EU POLICY CONTEXT



# EHDS – links with other legal proposals and initiatives

## GDPR

*EHDS builds upon GDPR rights and further develops some of them*

## European Health Union

*EHDS will boost the work of EU Cancer plan, HERA, Pharmaceutical Strategy for Europe*

## Data Governance Act, Data act

*EHDS complements and provides more tailor-made rules for the health sector*

## EU cybersecurity framework (NIS directive)

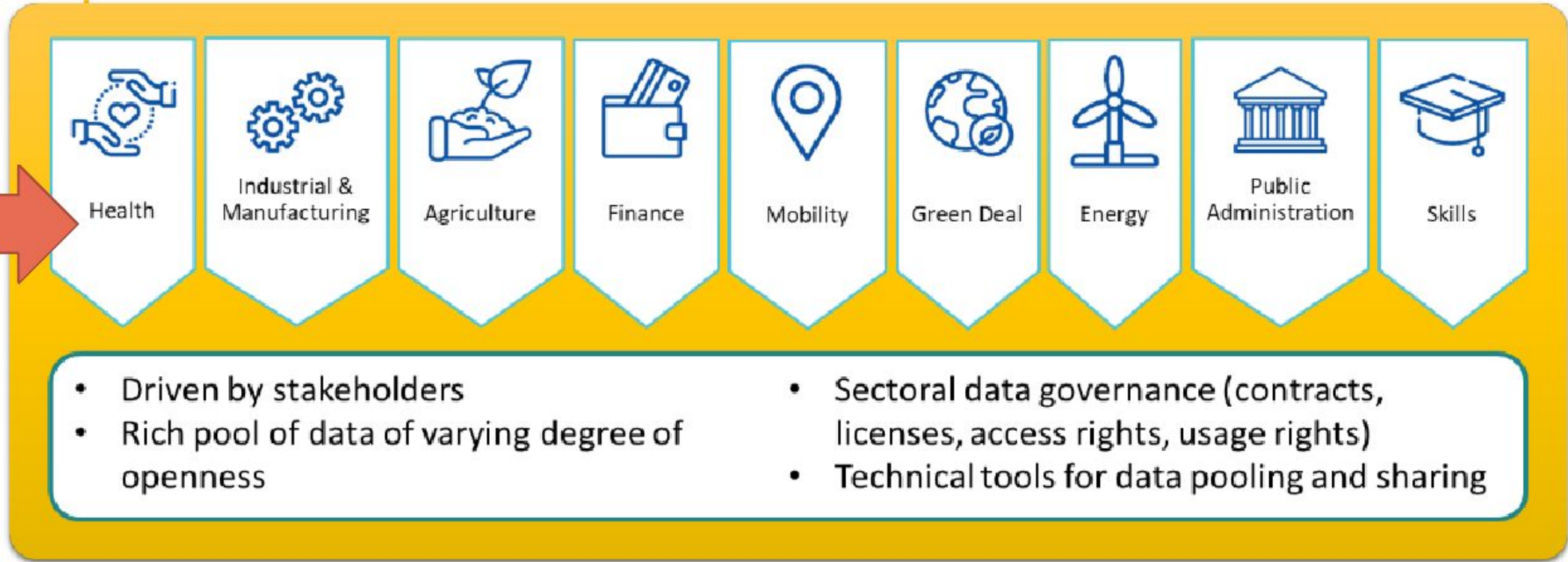
*EHDS complements and provides more tailor-made rules for the health sector*

## Artificial Intelligence Act

*EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality*

## Medical Device Regulations

*If manufacturers claim interoperability of devices with EHR systems – EHDS requirements apply*

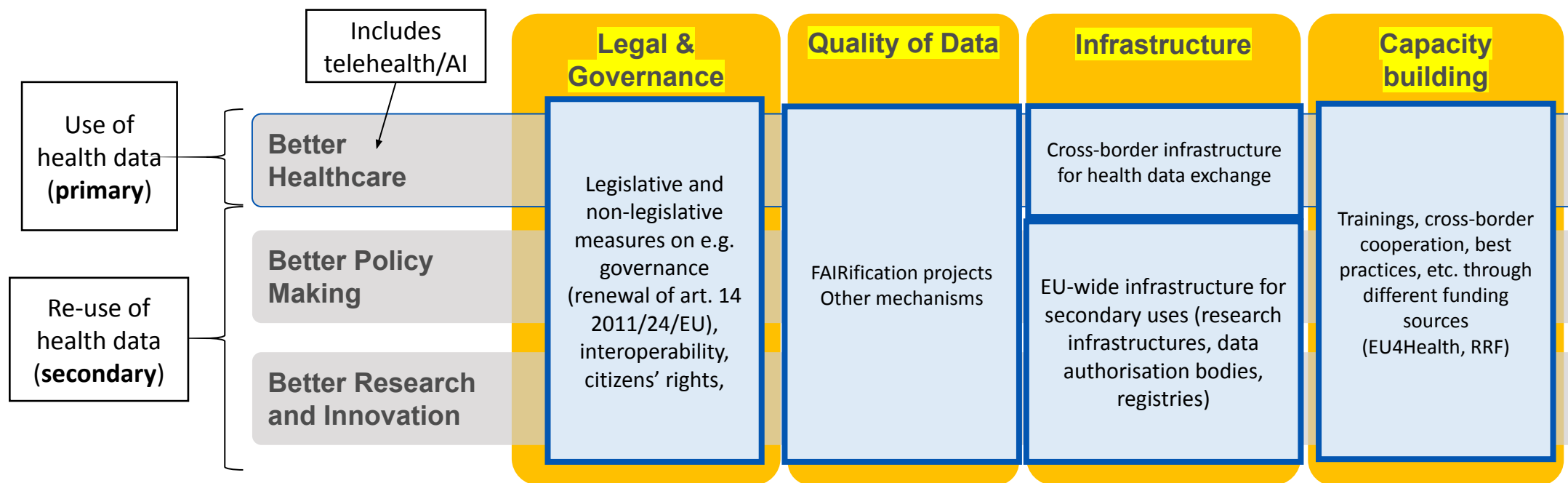


Personal data spaces

High Value Datasets from public sector



# USO DEI DATI SANITARI



# PRINCIPALI OBIETTIVI DELL'EHDS

1. Facilitare l'**accesso** alle cure
2. Aumentare la **qualità** dei servizi sanitari
3. Rendere più efficiente l'**erogazione** delle prestazioni
4. Sviluppare **nuove cure**
5. Sostenere il **mercato** delle tecnologie
6. Consentire all'UE di guadagnare fino a **11 mld** euro in 10 anni

# I DUE PILASTRI DEL REGOLAMENTO EHDS

## I. Uso primario dei dati sanitari (MyHealth@EU)



- Persone con accesso (e controllo) propri dati
- Cartelle cliniche elettroniche certificate UE
- Scambio transfrontaliero FSE
- Etichettatura delle App per il benessere

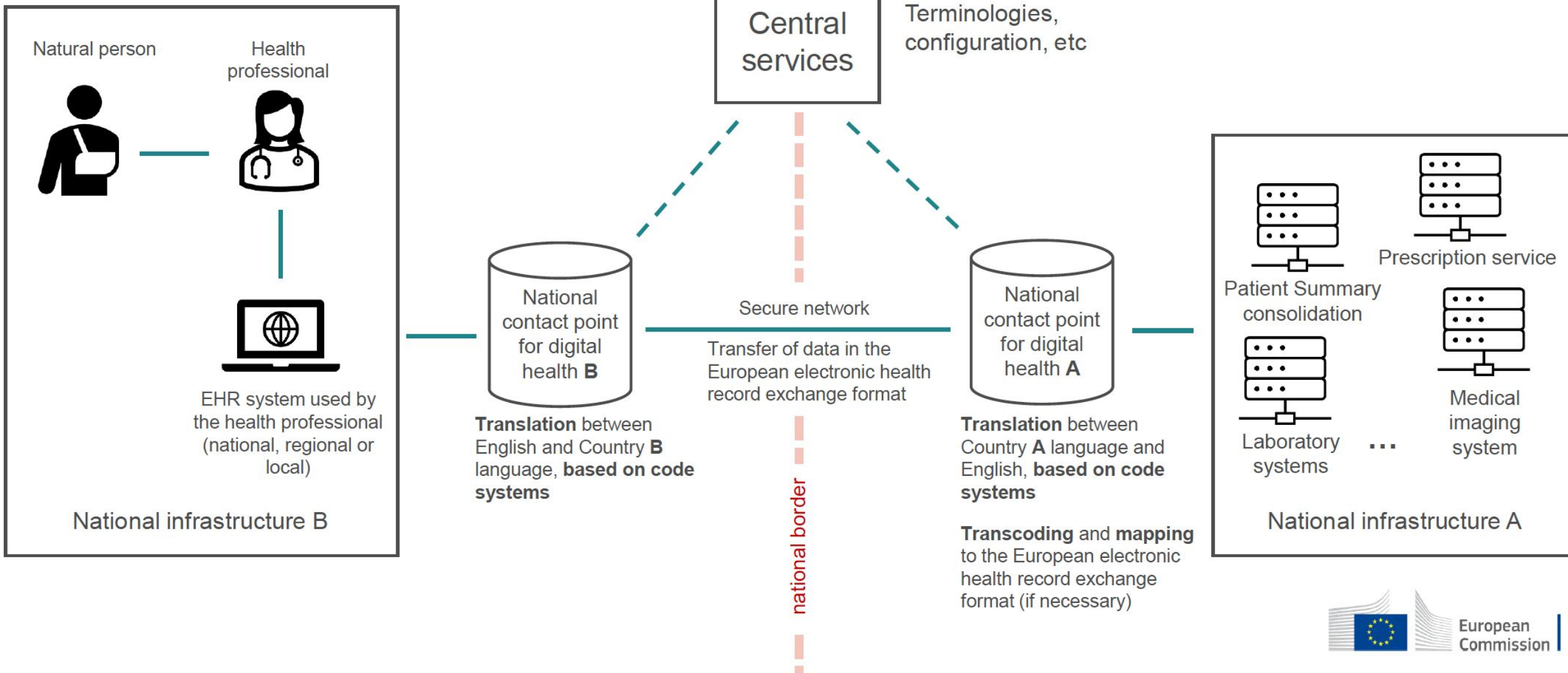
## II. Uso secondario dei dati sanitari (HealthData@EU)



- Introduzione uso secondario dati sanitari elettronici nell'UE
- Creazione di ambienti sicuri di elaborazione
- Descrizione precise finalità d'uso e usi proibiti
- Monitoraggio delle autorizzazioni accesso

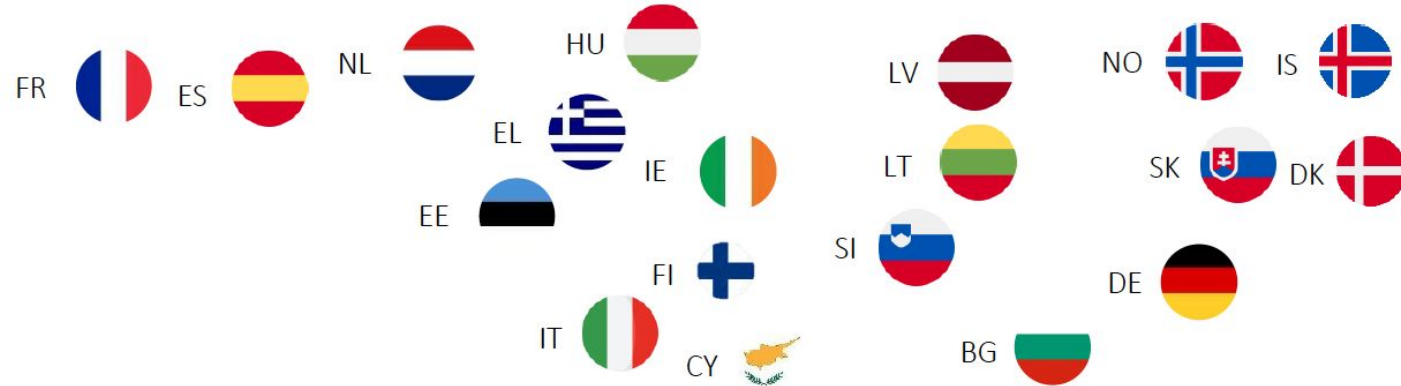
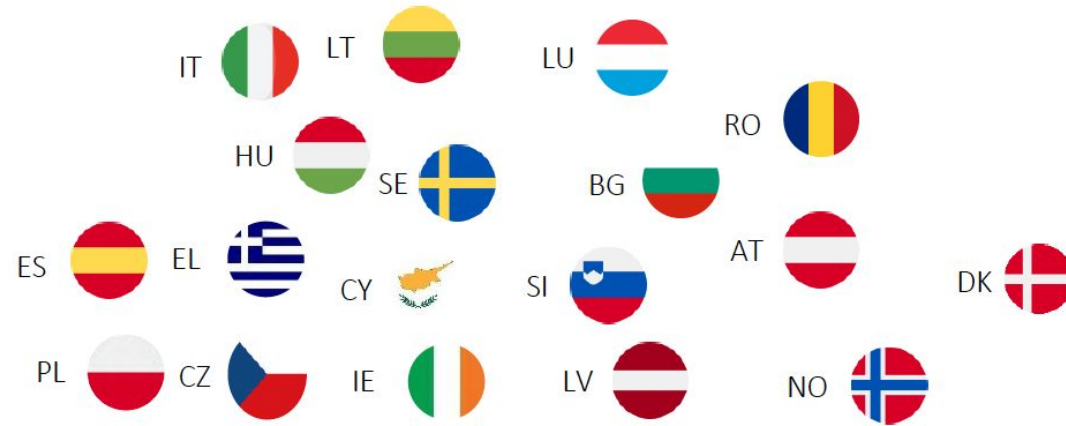
Uso primario: la cura del  
paziente





**Additional services to be added**

**ePrescription**



**Patient Summary**

**Timelines are approximate and subject to change**

Uso secondario: opportunità per  
la Sanità Pubblica (e non solo)

# USO SECONDARIO DEI DATI E SANITÀ PUBBLICA

## Capo IV, Art. 34, Regolamento EHDS

a) ..attività per motivi di pubblico interesse nell'ambito della **sanità pubblica e della medicina del lavoro**, quali la **protezione da gravi minacce** per la salute a carattere transfrontaliero, la **sorveglianza della sanità pubblica** o la garanzia di elevati livelli di **qualità e sicurezza dell'assistenza** sanitaria e di medicinali o dispositivi medici;

...

1. **Ricerca**
2. **Innovazione**
3. **Supporto decisionale**
4. **Sicurezza delle cure**
5. **Politica sanitaria**

# ALCUNE TRA LE POSSIBILI FINALITÀ

## Medicina di Precisione

**Studi familiari:** es. variazioni fenotipiche di malattia correlate a diverse esposizioni ambientali

**Programmazione sanitaria:** es. stima dei contributi della genetica e dell'ambiente al costo aggregato dell'assistenza sanitaria e al carico di comorbidità

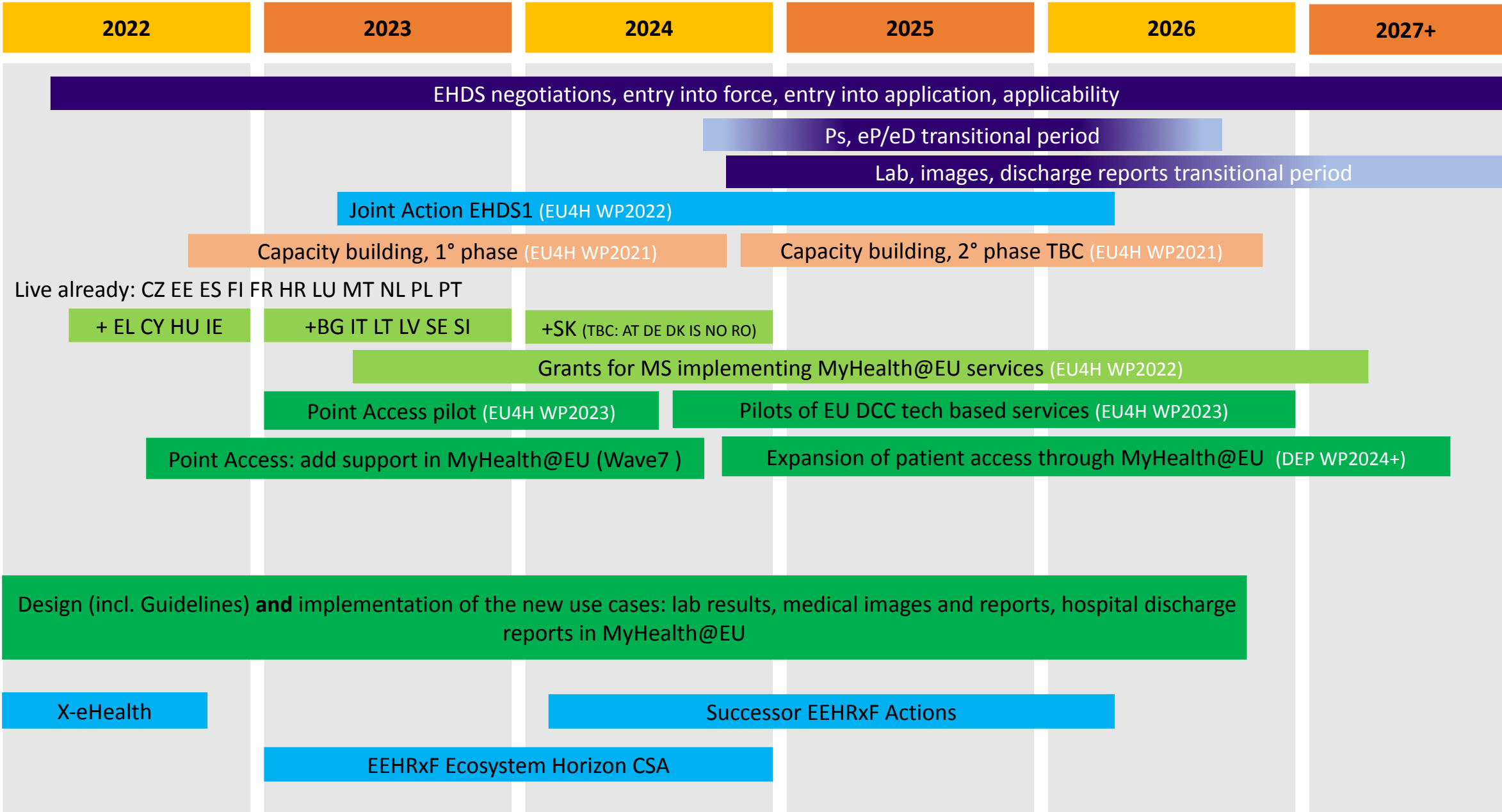
## Medicina Predittiva

**Associazione genica:** es. analisi di biobanche per scoprire associazioni tra nuove varianti geniche e fattori di rischio di malattia

**Modelli predittivi:** es. sorveglianza in tempo reale applicata a modelli per rilevare precocemente minacce per salute pubblica come nuovi focolai virali

## Medicina Preventiva

- **Studi di Popolazione:** es. interventi mirati in base a rischi specifici di popolazioni target con comportamenti a rischio
- **Apprendimento Sanitario:** es. sistemi di sorveglianza e pianificazione data-driven per ridurre ridurre errori sanitari e eventi avversi come ICA e AMR





Fidelia Cascini

# GRAZIE PER L'ATTENZIONE

[fidelia.cascini1@unicatt.it](mailto:fidelia.cascini1@unicatt.it)

[www.fideliacascini.com](http://www.fideliacascini.com)

