CONNECT UNIVERSITY

How can our digital transformation serve people's health?

Introduction

Mr Eric PETERS,

Head of Unit (acting), Unit B.2., Digital Decade Coordination

DG CONNECT, European Commission

The need to shape a successful digital transformation

2020 State of Union Speech

- *"We must make this Europe's Digital Decade. We need a common plan for digital Europe with clearly defined goals for 2030, such as for connectivity, skills and digital public services. And we need to follow clear principles: the right to privacy and connectivity, freedom of speech, free flow of data and cybersecurity."*

2021 Digital Assembly

President von der Leyen's speech

- *"We believe in a human-centred digital transition."*
- *"Digital technologies play a key role to accelerate access to knowledge and education, for equality and participation and for economic and job creation."*
- *For our Digital Decade to be successful, we need to build more, strong, international, digital partnerships"*

A clear policy response

The Digital Decade Policy Programme (DDPP)

- ✓ **The first ever digital strategy commonly agreed by EU institutions** with a multilevel governance – a significant breakthrough after the Digital Agenda and Digital Single market
- ✓ **Confirms and operationalises the vision of a Digital Compass communication** for Europe's digital transformation by 2030
- ✓ Puts digital governance **on a par with energy union**

Declaration on the Digital rights and principles

1. Putting people at the centre of the digital transformation: technology should serve and benefit all people living in the EU and empower them to pursue their aspirations, in full security and respect of their fundamental rights

2. Solidarity and inclusion: solidarity and inclusion through Connectivity; Digital education and skills; Working conditions; Digital public services online

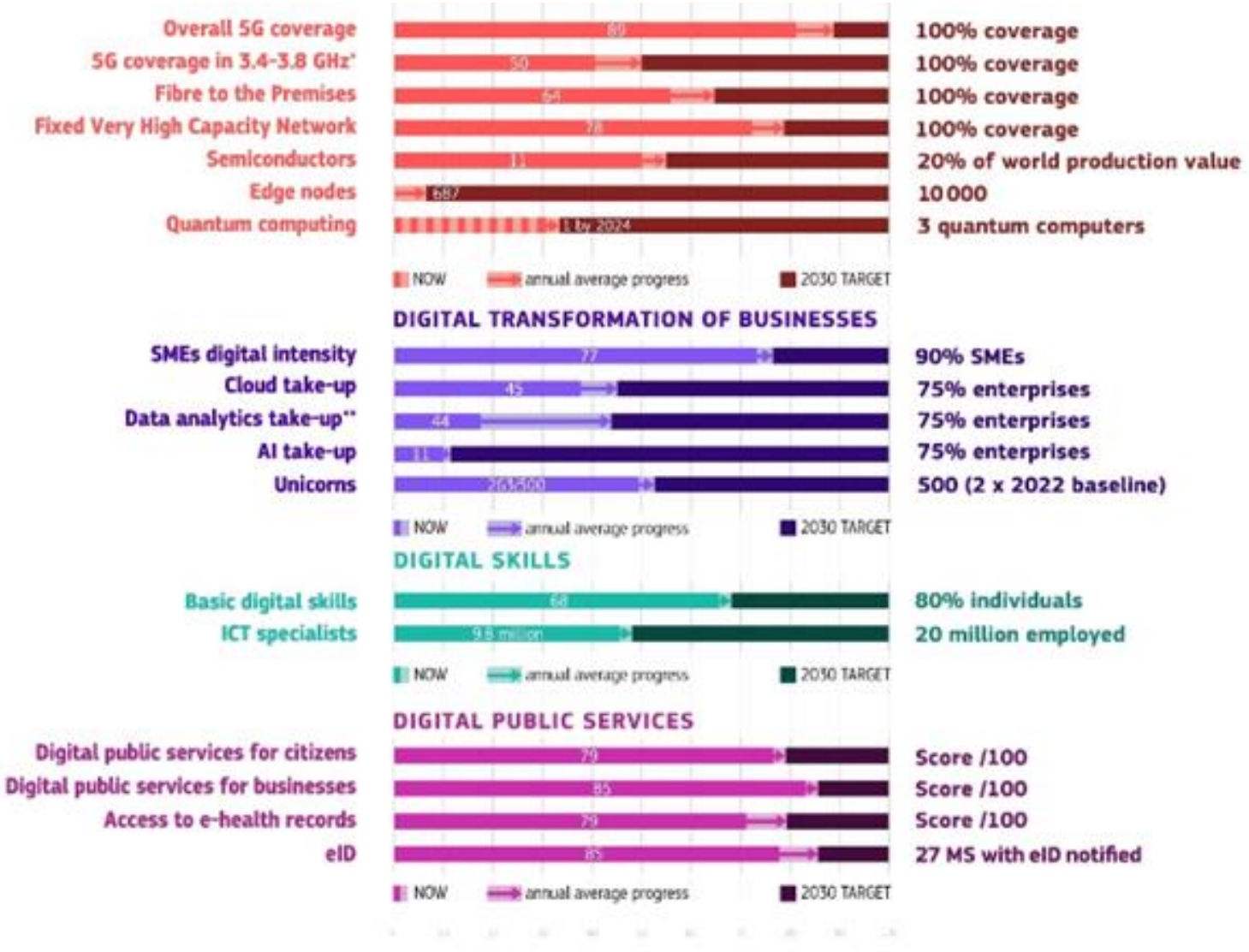
3. Freedom of choice: freedom of choice in interactions with artificial intelligence systems and in a fair digital environment

4. Participation in the digital public space: access to a trustworthy, diverse and multilingual digital environment; freedom of expression in the digital environment; transparency about media owners; very large online platforms should mitigate the risks from e.g., disinformation

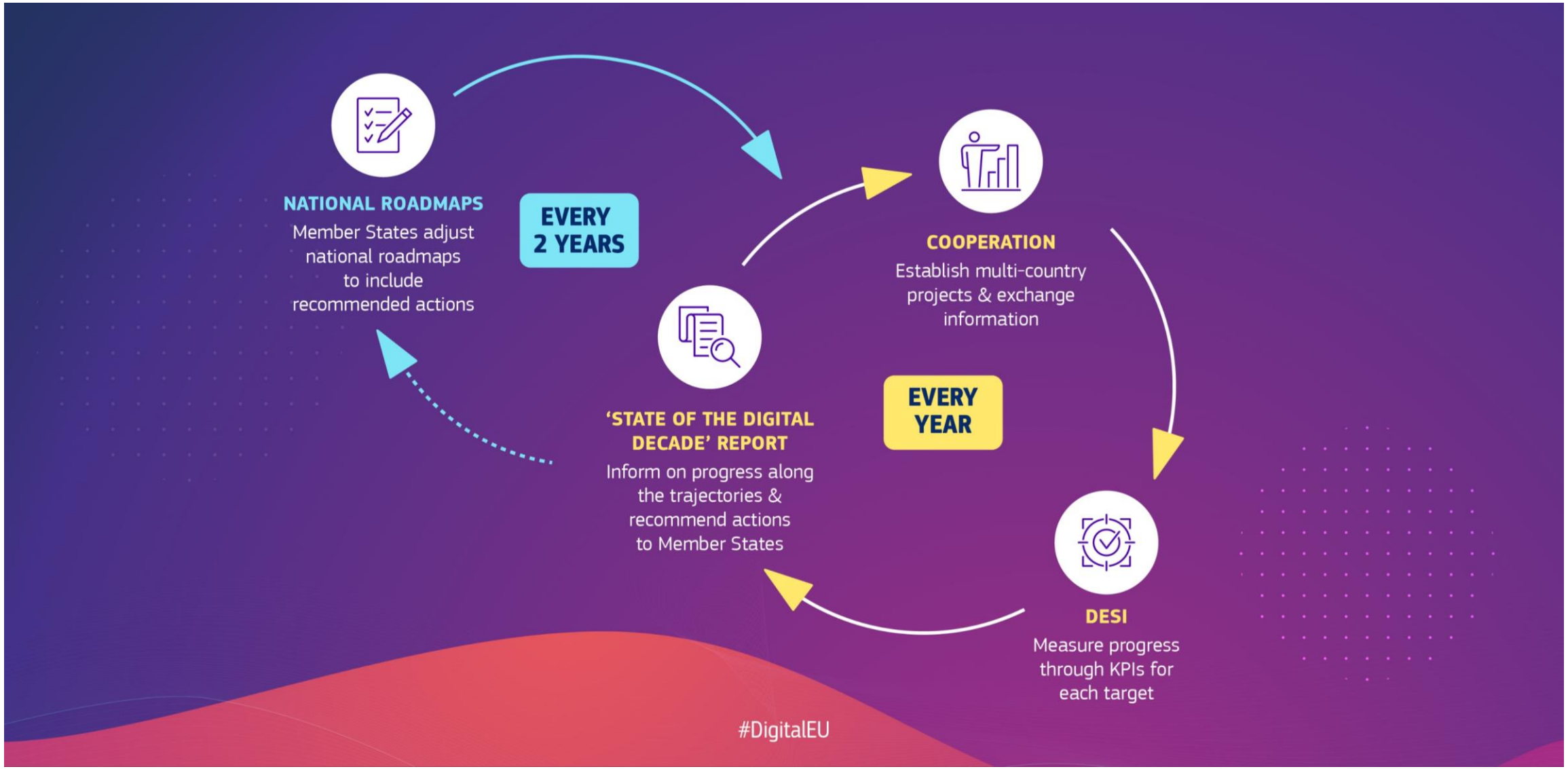
5. Safety, security and empowerment: a safe and secure online environment, with particular attention to children and young people; ensuring privacy and individual control over data

6. Sustainability: digital products and services should be designed, produced, used, disposed of and recycled in a way that minimises their negative environmental and social impact; access to accurate, easy-to-understand information on their environmental impact and energy consumption

Digital Decade Targets: Taking stock of progress



DDPP Governance



Health Data

- ✓ The Digital Decade Policy Programme establishes the **target of 100% of Union citizens with access to their electronic health records**.
- ✓ **4/5 respondents consider digital technologies to be important by 2030 for accessing or receiving healthcare services**
- ✓ **Health data and advanced technologies have a great potential** to improve access to health services by citizens, increase quality and efficiency of healthcare, develop personalised approaches and support research and innovation.
- ✓ **The successful conclusion of the political negotiations for on the European Health Data Space Regulation is an important milestone** to further reinforce progress in this area and empower and benefit citizens
- ✓ The Commission has also put forward **several initiatives on health data infrastructures and research and innovation** in the area of health.

Digital technologies & Mental health

SAVE THE DATE

CNECT University Session - September 2024

- The attention on the health dimension of digitalisation has also exposed the fact that digital tools can have negative impacts on health, in particular mental health
- Legislations was adopted recently, notably the Digital Services Act which offer tools to address such impact on very large online platforms, or the Audiovisual Media Services Directive (AVMSD) and Digital Service Act (DSA) which seek to protect the privacy and safety of minors
- This matter will be discussed further in a dedicated session in September 2024

Access to Health data

Health data:
Opportunities & challenges in the strategic context

Ms Saila RINNE,

Head of Unit (acting), Unit H.3., eHealth, Well-Being and Ageing

DG CONNECT, European Commission

Digital Health – opportunities and challenges

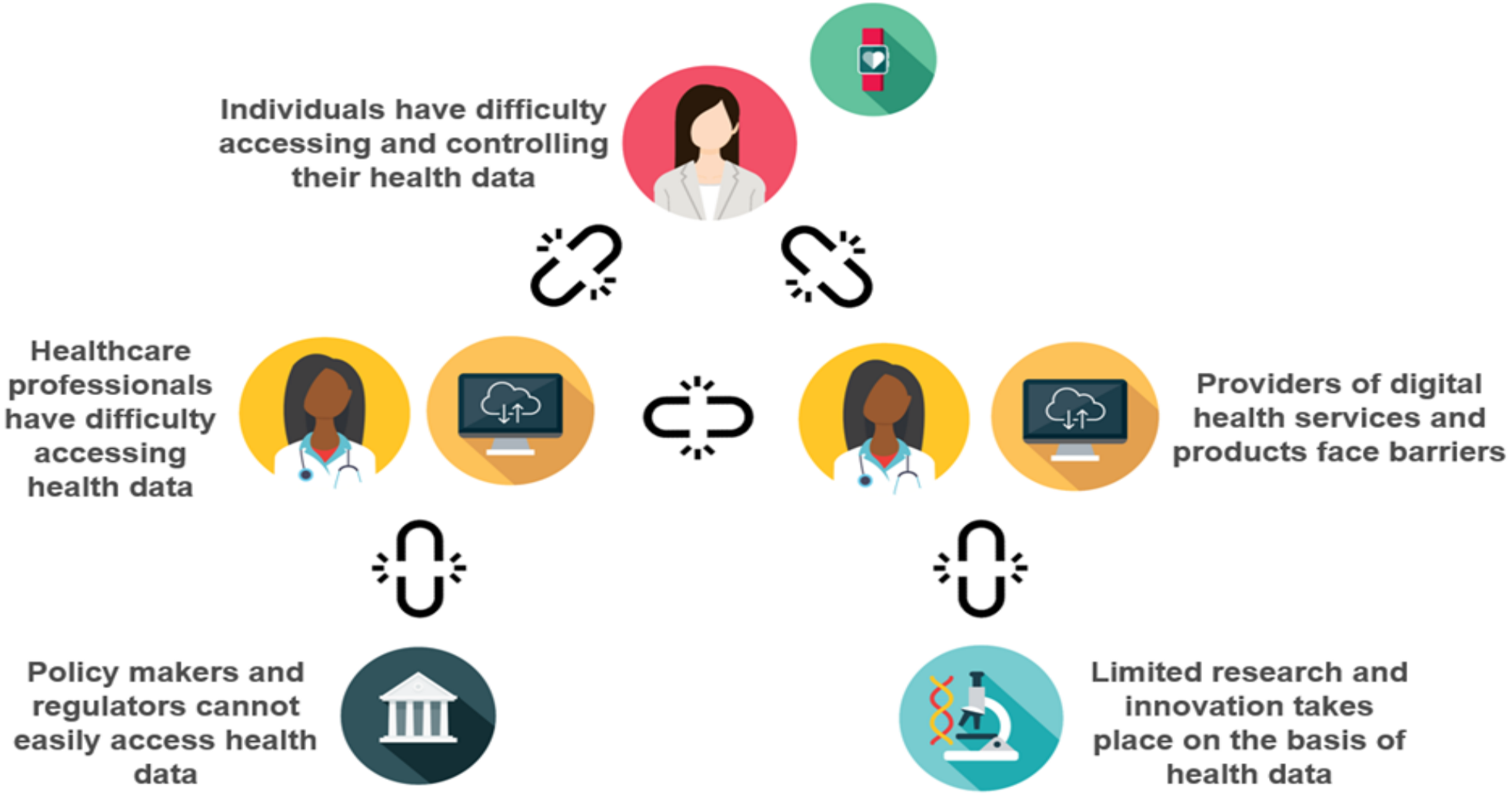
Opportunities

- Citizens are in **control** of their own health data and can **access** them across borders
- Better, faster **diagnoses**, fostering **personalised medicine** and **preventive approaches**
- Increasing **efficiency** of healthcare systems, currently under pressure
- Make health services more **accessible**, including in remote areas
- Harnessing health data for **research** and **innovation**, increasing competitiveness of the EU e-health industry

Challenges

- Gaining public **trust** towards digital health solutions – *reliability, trustworthiness, safety* including of **AI in health**
- Granting **privacy** and **data protection** to citizens
- **Digital skills** and **digital health literacy** among users and healthcare professionals
- **Interoperability** between digital health systems and infrastructures

Main challenges in harnessing the power of health data



Personalised Medicine

Technology

Regulatory framework

Healthcare implementation

Skills

Citizens' trust

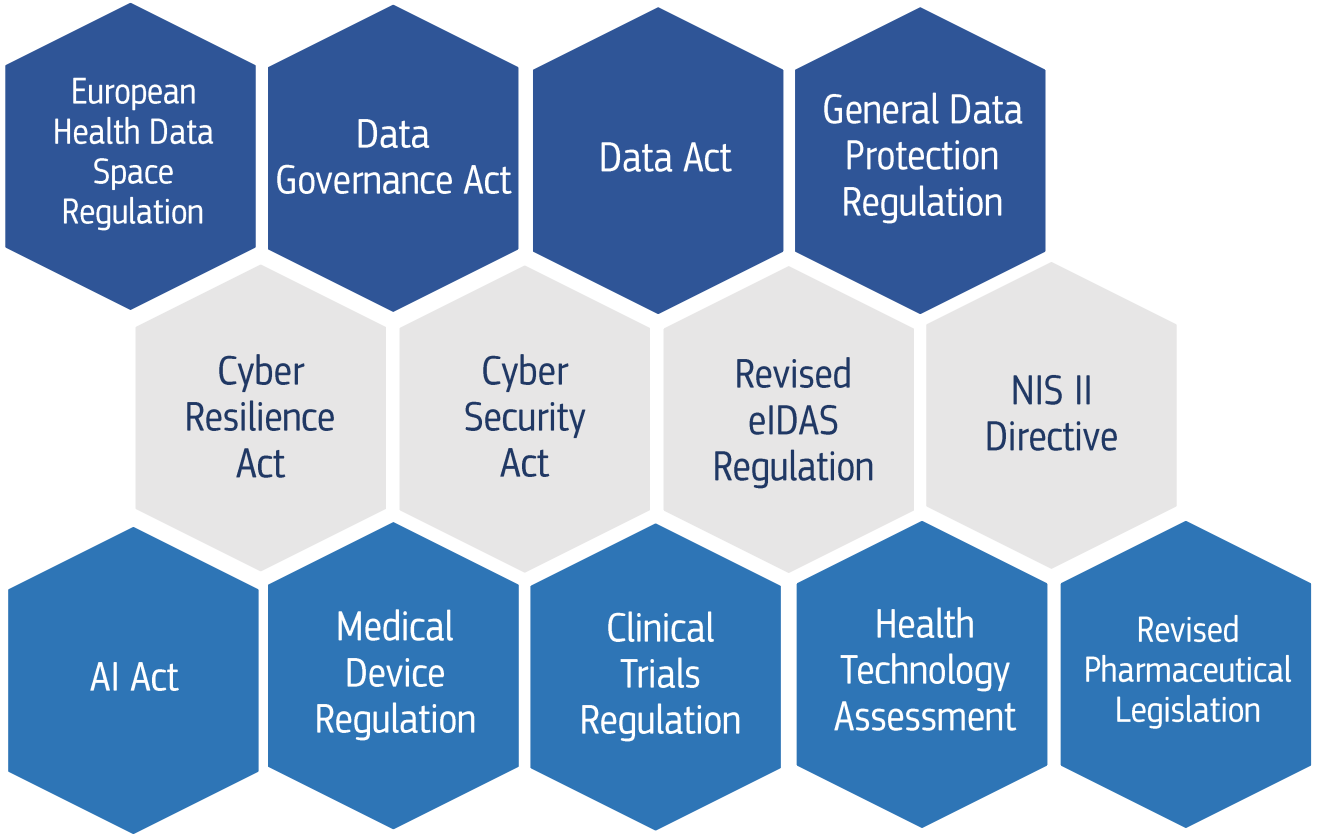
Data

Digital transformation of healthcare: the building blocks

Data availability & sharing

Security and trust

Safety and technology



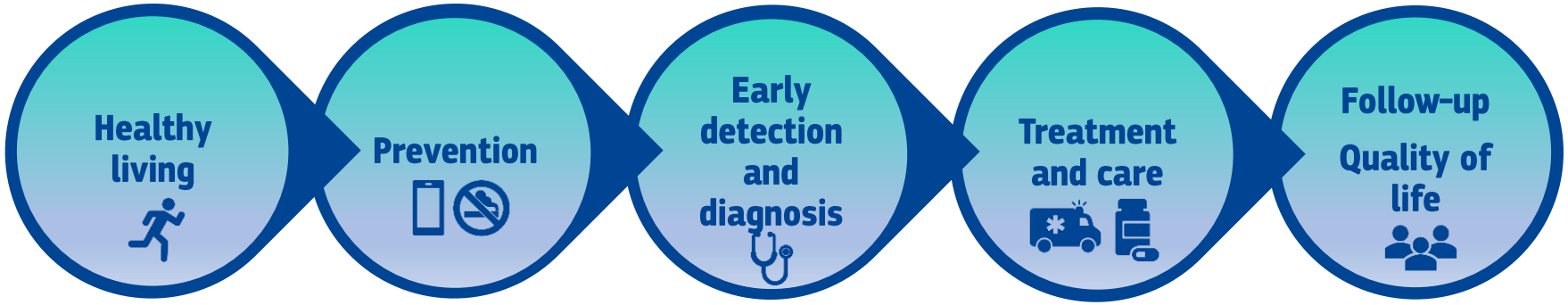
e-Health target:
100% of EU citizens access to **electronic health records** by 2030

Digital health solutions can deliver a triple win for Europe

Improving the health and quality of life of Europeans, including older people

Supporting the long-term sustainability and efficiency of health and social care systems

Enhancing the competitiveness of EU industry through business and expansion in new markets



Digital Europe Programme deploying health infrastructures and AI

Cancer Imaging Initiative

- Links resources and databases to establish an **open infrastructure** of cancer images
- Fosters innovation and deployment of digital technologies, **including AI-based tools**, for improved clinical decision-making, diagnostics, treatment and prediction

1+ Million Genomes Initiative

- Secures access to **genomic data** and the corresponding clinical data
- Facilitates research, personalised healthcare and public health
- Enables the use of genomic data for innovation, for example for developing and training **AI models**

Virtual Human Twins Initiative

- Facilitates advanced research and technology development on Virtual Human Twins, including **AI foundational models**
- Ecosystem and **platform** for computational models of organs and organ systems
- Supports personalised care, prevention, better diagnosis and treatment

eHealth indicators:
The logic of the intervention and importance of key features for the users

Ms Renata PALEN,

Policy Officer - EU policies, Unit H.3., eHealth, Well-Being and Ageing

DG CONNECT, European Commission

A Digital Decade to shape EU's transformation

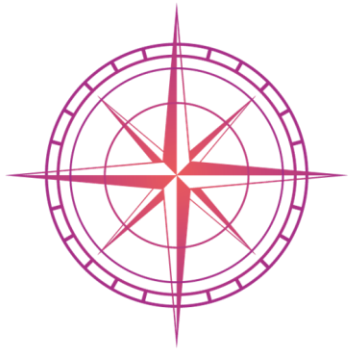
Vision

VALUES

TARGETS

Skills
ICT Specialists: 20 millions + more women in ICT
Basic Digital Skills: min 80% of population

Government
Key Public Services: 100% online
e-Health: 100% of citizens with online access to health records
Digital Identity: 100% citizens have access to digital ID



Infrastructures
Connectivity: Gigabit for everyone
Cutting edge Semiconductors: double EU share in global production
Data – Edge & Cloud: 10,000 climate neutral highly secure edge nodes
Computing: first computer with quantum acceleration

Business
Tech up-take: 75% of EU companies using Cloud, AI or Big Data
Innovators: grow scale ups & finance to double EU Unicorns
Late adopters: more than 90% of European SMEs reach at least a basic level of digital intensity

Action

GOVERNANCE MECHANISM
Annual reporting, recommendations
Digital Decade Board

MULTI COUNTRIES PROJECTS
agility to invest together in digital infrastructures (EDIC)

2030 Digital COMPASS Communication (March 2021)

Access to health data - user perspective

Empowerment of citizens having online access to their electronic health records translating into improved service quality, continuity of care and improved healthcare efficiency

Providers of health data in registries

Electronic health records data categories:

- Patient summary
- Electronic prescription
- Electronic dispensation
- Laboratory result
- Discharge report
- Medical image and medical image report

Patient summary – provides information on important health related aspects such as your allergies, current medication, previous illness, surgeries. Helps doctors to formulate an adequate treatment, avoid some possible risk (for instance in case of allergy).
Help patients to track the history of their treatments.

ePrescription - allows citizens to retrieve their medication in a pharmacy without having to bring the printed prescription.

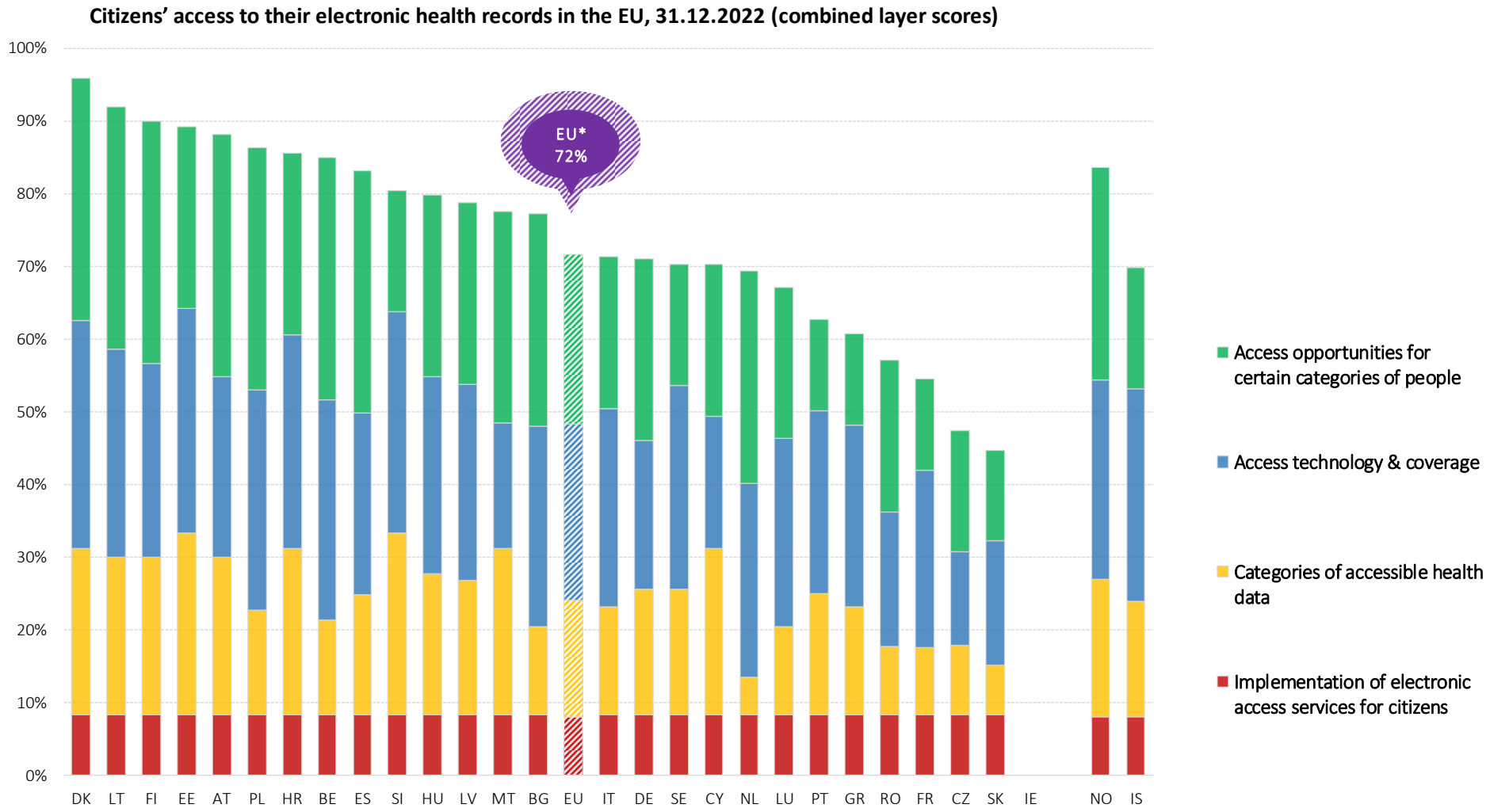
Lab results – results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, plus reports supporting the interpretation of the results.

Access to e-health records composite indicator used for DD is calculated as an average of 12 sub-indicators in 4 themes

KPI definition: the **nationwide availability** of online **access services for citizens** to their electronic health records data (via a patient portal, or a patient mobile app) with **additional measures in place** that enable certain categories of people (e.g. guardians for children, people with disabilities, elderly) to also access their data, and the **percentage of individuals** that have the ability to obtain or make use of their own **minimum set of health-related data** currently stored in **public and private electronic health-record (EHR) systems.**

Composite indicator	Digital Decade eHealth Composite Indicator			
Thematic layers	**1. Implementation of electronic access services**	**2. Categories of accessible health data**	**3. Access technology and coverage**	**4. Access opportunities for certain categories of people**
Sub-indicators	1. Nationwide availability of electronic access service(s)	2. Electronic health records summary data	5. Access to electronic health records with an eID	9. Access for legal guardians
		3. ePrescription/eDispensation data	6. Access via an online portal or mobile application	10. Access for authorized persons
		4. Electronic results and reports	7. Percentage of the national population able to access	11. Assistance for disadvantaged groups
			8. Healthcare providers connected and supplying relevant data	12. WCAG v2.1 and Web Accessibility Directive compliance

Citizens' access to electronic health records in the EU
EU-average in 2022



*EU-average does refer to average scores of the EU27 Member States.

The Electronic Identification (eID) and the digital wallet

The importance of the eID usage in the healthcare context

Ms Maya MADRID,

Policy Officer, Unit H.4., eGovernment and Trust

DG CONNECT, European Commission

EU Digital Identity Wallet

Agenda

01 **EU Digital Identity Wallet** General Overview

02 **EU Digital Identity Wallet** Large Scale Pilots (LSPs)

03 **EU Digital Identity Wallet** Health Use Case

01

EU Digital Identity Wallet

General Overview

EU Digital Identity Goal

The **2030 Digital Decade** policy programme sets out Europe's ambition for the **digital transformation by 2030**. The EU Digital Identity Wallet supports the achievement of the Digital Decade targets. In particular, by 2030, all key public services should be available online, all citizens should be able to access their online health records, and everyone should have access to secure privacy-enhancing eID.

2030 DIGITAL DECADE TARGET

100 % of Union citizens have **access** to secure electronic identification (eID) means that are recognised throughout the Union, enabling them to have full control over identity transactions and shared personal data.

What is the EU Digital Identity Wallet?

Introducing the

EU Digital Identity
Wallet

Your Data, Your Story.

The **European Commission's response** to the challenges of digital identification.

Will allow you to **securely identify yourself** online when accessing a wide range of public and private services.

Will let you **store, present and share electronic attestations** from university diplomas to train tickets).

Will let you **sign digital documents** swiftly and easily

Will be made available in **every EU Member State for citizens, residents and businesses.**

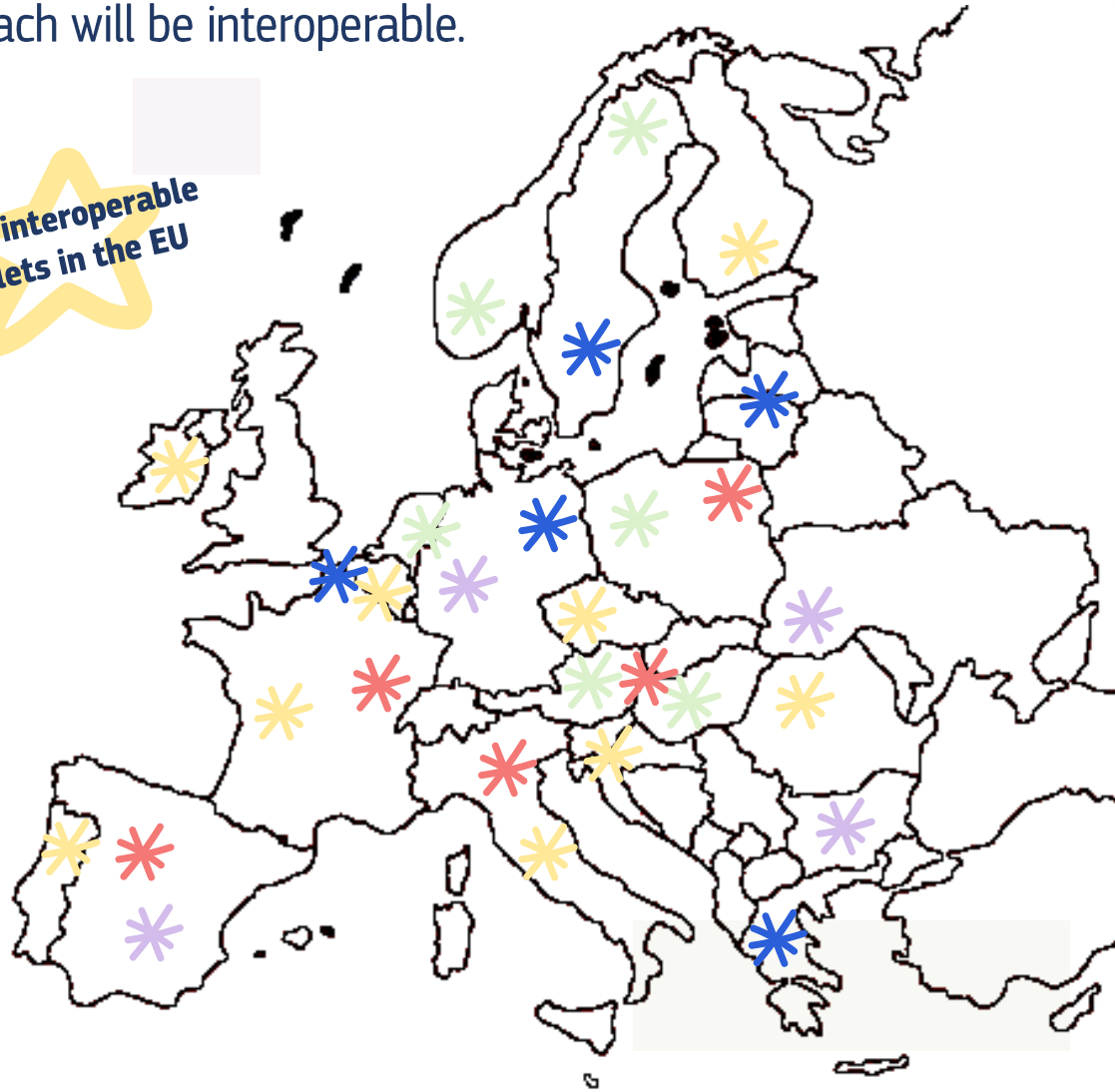
Open-source and interoperable

There will not be one EU Digital Identity Wallet, but many, built to one set of open specifications, created by the European Commission, together with Member States. Each will be interoperable.

One set of open specifications

One open-source reference implementation

Many interoperable wallets in the EU



Benefits of the EU Digital Identity Wallet

How will citizens, governments and relying parties benefit from the wallet? Securely store and share your digital identity — discover the many ways the EU Digital Identity Wallet will benefit both individuals and organisations.

Citizens

Protect personal data
Simplify paperwork and admin
Access public and private services across borders

Governments

Improve access to digital services
Enhance fraud prevention
Improve security

Relying Parties

Improve security and privacy
Reduce cost of authentication
Avoid relying on competing big platforms

Society

Increased online transactions
Resource reallocation
New business opportunities
Economic growth

Characteristics of the EU Digital Identity Wallet

What is EU Digital Identity Wallet?

Free use for all EU citizens

Provided by Member States, all EU citizens may use it for free on a voluntary basis.

Accepted throughout the Union

Recognised by private and public service providers (relying parties) for all transactions that require authentication.

Secure and privacy oriented

Citizens can control and protect their identity, personal data and digital assets.

Functions of the EU Digital Identity Wallet

What can you do with the EU Digital Identity Wallet?

Identification & authentication

Identification and authentication to access public and private services, payment authorisation, KYC

Store & present attestations of attributes

Present educational diplomas/reports for enrolling at university; present your driving license for renting a car

Sign & seal electronically

Sign a banking agreement

EU Digital Identity Wallet stakeholders

The roles and responsibilities of the parties in the EUDIW ecosystem are outlined in the EUDI Regulation and the ARF.

Member States

Governmental Bodies
Data protection authorities
Conformity assessment bodies
Policy makers

Wallet Providers

Wallet providers that **offer the core functionalities of the wallet and provide ongoing technical support**

Digital ID / Digital Credentials Issuers

Any trusted organisation that can **issue your Digital ID / Digital Credentials**

Wallet Users

European citizens, residents & businesses

Service providers

Public & private organisations which will both **issue credentials & verify them**

What will happen in practice?

Implementation, set up and use of the EU Digital Wallet

Implementation

Set up

Use

Member States

1 mandate

Wallet Provider

2 build

3 serve

3 download

Wallet User

4 issue

5 request

6 present

PID & Attestation Issuer

Relying Parties

Trust System

7 verify status

EUDI Wallet Roadmap

LEGAL

- **2014** — Adoption of the eIDAS 1 regulation
- **2020** — Public consultation on eIDAS regulation launched
- **2021** — Commission adopts the recommendation for a common EU toolbox
- **2021** — Commission adopts the proposal for a regulation establishing the European Identity Framework
- **2022** — Legislation progresses (EP draft report, toolbox process...)
- **2023** — Legislation trilogues
- **2024** — **Legislation adoption; Implementing Acts**

TECHNICAL

- **2021** — Toolbox process begins
- **2022** — Technical progress
- **2023** — Designing and Testing the Wallet
- **2024** — Building the Wallet
- **2025** — First Member States wallets made available
- **2026** — **Wallets widely available in all Member States**

02

EU Digital Identity Wallet

Large Scale Pilots

Examples of wallet use cases

ACCESS GOV SERVICES

Access digital public services (nationally and across borders) by using your wallet to securely identify and authenticate yourself.

MOBILE DRIVING LICENCES

Request a digital version of your driving license. Then always have it ready to share in your wallet.

EDUCATION

Never lose the university diploma you worked so hard for again. Easily store and share your most important education credentials.

HEALTH

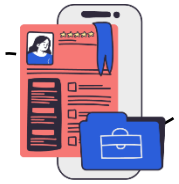
Keep your health close at hand. Identify yourself at your pharmacist's and claim your needed prescriptions with just your wallet.

TRAVEL

Store and share key travel documents in your wallet. Prove who you are when booking a hotel online, and then easily check-in once you get there.

ACCESS SOCIAL SECURITY

Keep tabs on your social security information and use your wallet to access the social security benefits you are entitled to.



ORGANISATION ID

Use your wallet to prove who you work for when meeting new and potential clients.

REGISTER SIM

Registering a new SIM card just got easier. Your wallet lets you quickly identify yourself.

OPEN A BANK ACCOUNT

No need to track down to a bank branch. Verify your identity when opening a new bank account with just your wallet.

PAYMENTS

Make your online transactions easier. Use your wallet to identify yourself and authorise payments.

AGE VERIFICATION

Your wallet can provide proof of age when requested, without disclosing any information about your identity.

CONTRACTS

Your wallet makes business flow. Sign contracts with just your wallet.

Large Scale Pilot Overview

Large Scale Pilots are test-driving the EU Digital Identity Wallet

NOBID CONSORTIUM

A set of Nordic and Baltic countries who, together with Italy and Germany, who are developing a large-scale pilot for the payment use case in the EU Digital Wallet.

PAYMENTS

Potential
For European Digital Identity

Potential is a secure digital ID that will allow citizens to quickly and securely prove their identity as part of their online citizenship procedures.

MOBILE DRIVING LICENSE

ACCESS GOV SERVICES

OPEN BANK ACCOUNT

HEALTH

CONTRACTS

SIM REGISTRATION

EWC

The EWC aims to harness EU digital identity benefits for Digital Travel Credentials across Member States, building on the Reference Wallet Application for this specific use case.

PAYMENTS

TRAVEL

ORGANISATION ID

DC4EU

DC4EU supports the education and social security sectors by integrating cutting-edge digital services across Europe within a cross-border trust framework.

EDUCATION

SOCIAL SECURITY

Large Scale Pilot New Call Publication (2025-2027)

The new call for large scale pilots has been published on 07/05 by HaDEA on the **EU Funding & Tenders Portal**.

This call, **"European Digital Identity and Trust Ecosystem (Standards and Sample Implementation)"** will provide support for the piloting and deployment of the EU Digital Identity Wallet around **4 priority use-cases areas.**

Wallets for Businesses

Business-to-business and business-to-government scenarios including regulatory compliance, company registration, and power of attorney

Wallets for Travel

National and Cross-border travel scenarios including local public transport, long-distance travel, shared mobility border control, hotel check-in

Wallets for Payments & Banking

Payment and banking scenarios including a standardised process for Know-Your-Customer, Strong Customer Authentication, and offline transactions and processes

Wallets for Age Verification

Age verification scenarios including the issuance of a pseudonymous attestation containing only age information by a trusted third party

03

EU Digital Identity Wallet

Health Use Case

Health Use Cases

- ePrescription was initiated to develop a solution for eHealth cases for national and cross-border usage.
- **Users should be enabled to access their health information** digitally and be in control to give or revoke access to their personal health data.
- **Healthcare professionals should be enabled to store their professional credentials** in the Wallet.

ePrescription's aim is to **pilot national and cross-border eHealth cases**, providing citizens with access to their health information through Mobile Phones.

Health Use Case

ePrescription: A secure and paperless way to manage medical data and prescriptions.

Potential
For European Digital Identity

Co-funded by the European Union

- **POTENTIAL is piloting the Health use case** with 10 member states participating: **France, Austria, Cyprus, Czechia, Greece, Hungary, Italy, Poland, Portugal, Spain and Ukraine.**
- Diverse mix of stakeholders, including **various health institutions, ministries, and organisations** focused on development and digital transformation, fulfilling roles such as Working Institutions, Coordinating Institutions, and Research Partners.
- Italy leads in the number of stakeholders, with important contributions from governmental health institutions and national eHealth centers.
- Efforts are **supported by service providers specialising in digital payment, identification, and health services.**

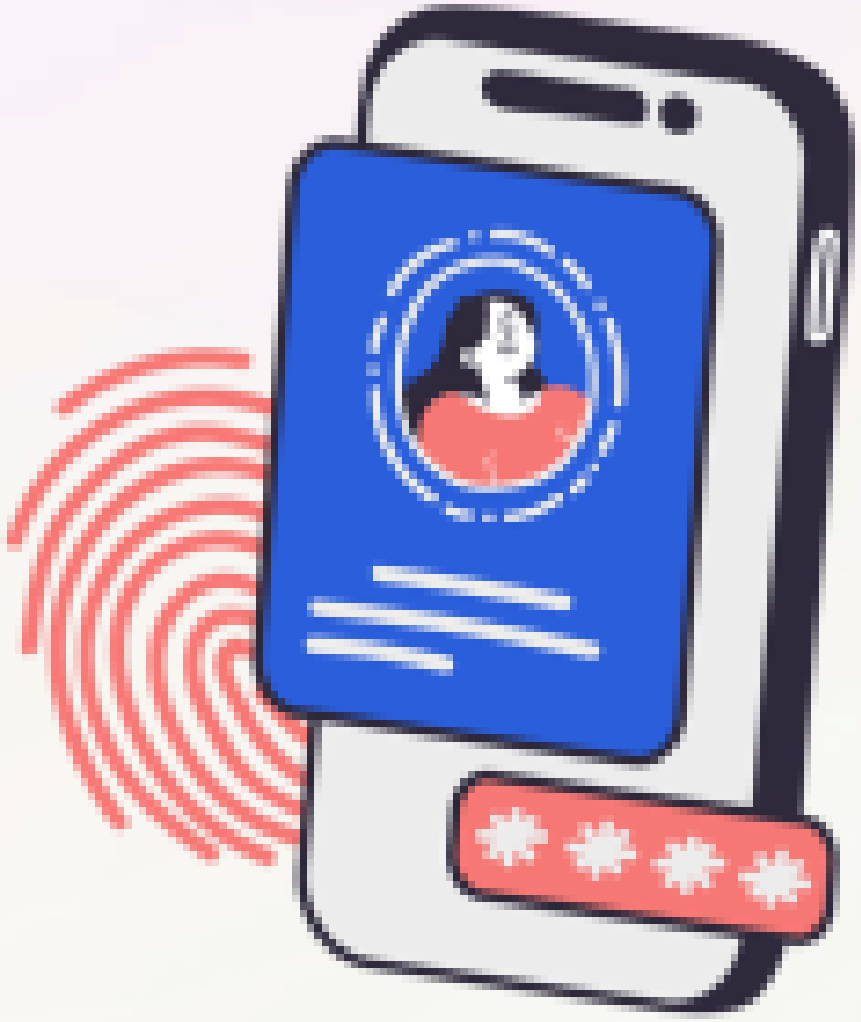
European Commission | EU Digital Identity Wallet

Thank you!

Questions?

For more information you may visit

[EU Digital Identity Regulation]
[GitHub]
[EU Digital Identity Wallet website]



Introducing the European Health Data Space (EHDS) Regulation: use and re-use of health data

Mr Konstantin Hyppönen,
Programme Officer, CNECT H.3, e-Health, Well-Being and Ageing,
DG CONNECT, European Commission

Mr Owe Langfeldt,
Policy Officer, SANTE C.1, Digital Health,
DG CONNECT, European Commission

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

3. **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.

Rights of natural persons in primary use

The rights apply in both national and cross-border contexts

Access health data

Appoint an authorised person to access data

Download a copy of data

Request rectification

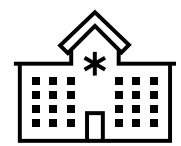
Set access restrictions

View access logs

Insert information into EHR

Opt out from data sharing (where enabled by MS)

Health data access service (portal or app)

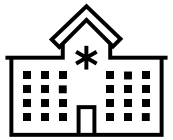


Registration of data

Natural person

Provide a copy of data

Another portal or app



Access to data

Access by treating health professional through the health professional access service (via MyHealth@EU or national solutions)

Data categories for primary use

Priority **categories**

- Patient summaries
- Electronic prescriptions
- Electronic dispensations
- Medical imaging: studies and reports
- Medical test results: laboratory, other diagnostics, related reports
- Discharge reports

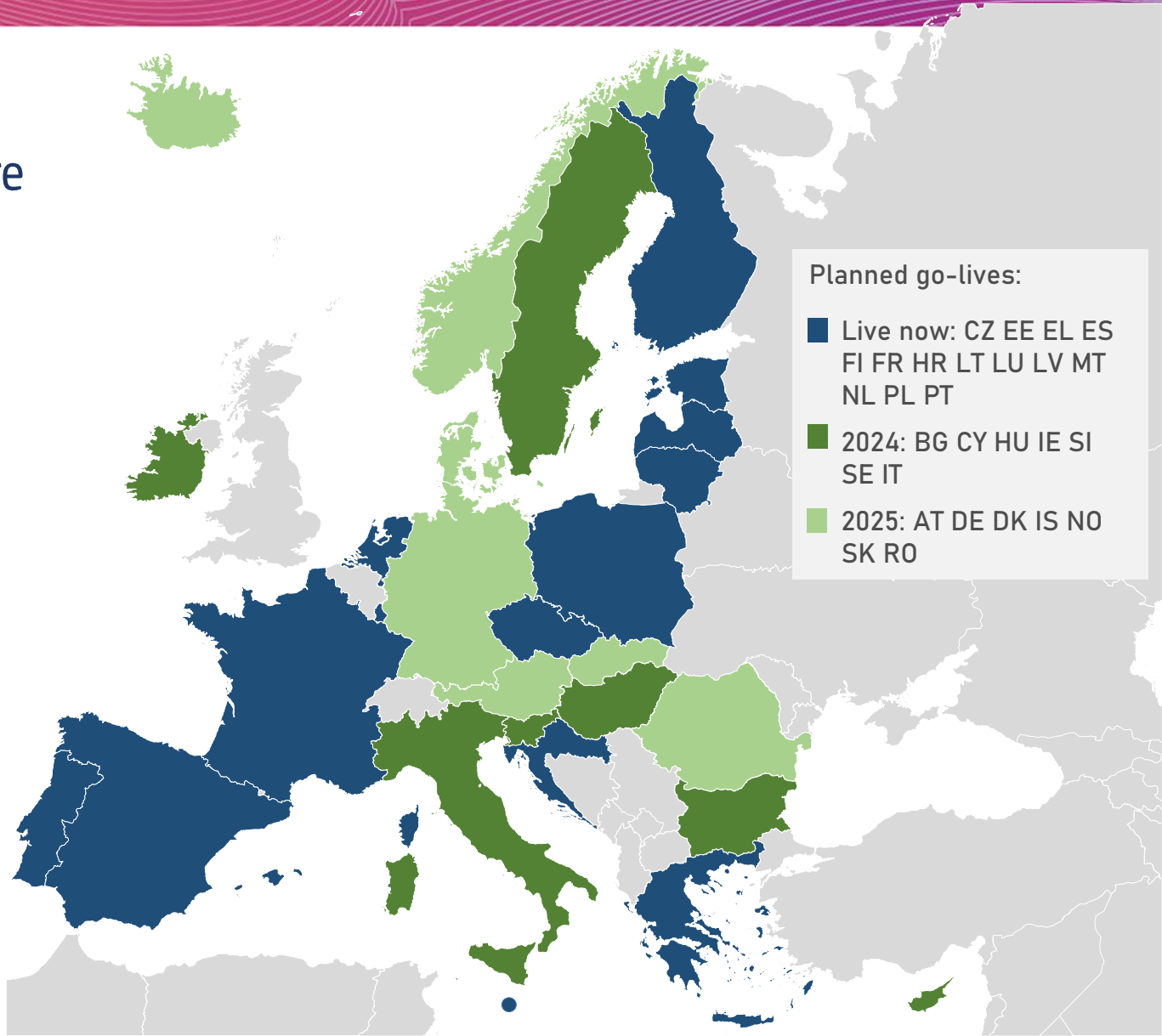
Full implementation of the rights of natural persons *shall* be ensured.

Additional **data categories**

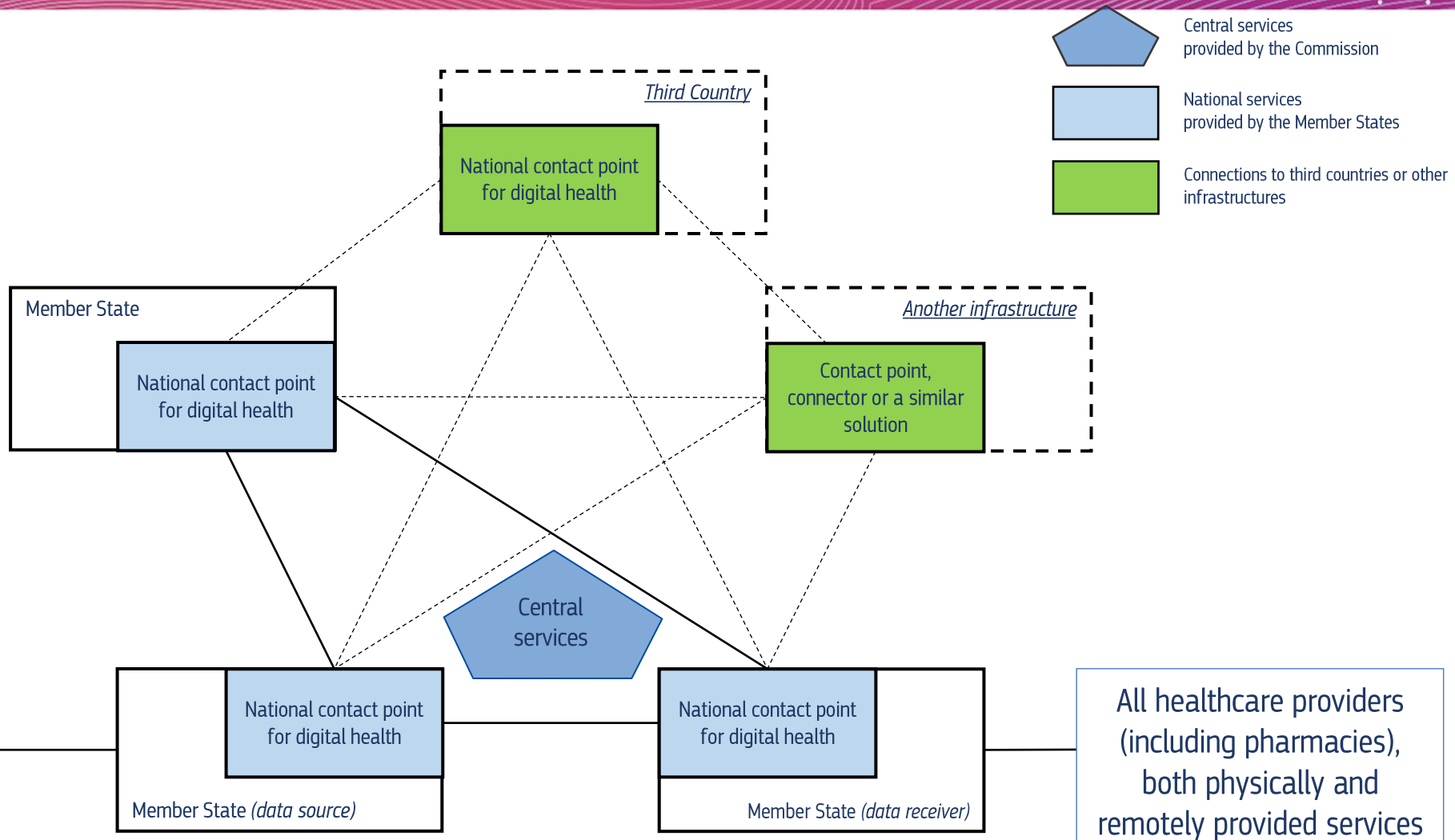
- *May* be defined by MS
- When defined, all rights of natural persons *shall* be implemented at national level in respect to these
- Support *may* be included in the European format
- *May* be exchanged through MyHealth@EU (where supported)

Cross-border infrastructure MyHealth@EU

- MyHealth@EU is the existing infrastructure that connects healthcare providers in 14 Member States.
- The current live services are: (1) Patient Summaries and (2) ePrescription and eDispensation.
- These services will be expanded to all priority categories in the EHDS.



MyHealth@EU high-level architecture



Data categories

Priority group 1:
- Patient summaries
- ePrescriptions and eDispensations

Priority group 2:
- Medical test results: laboratory, other diagnostics, related reports
- Medical imaging: studies and reports
- Discharge reports

Additional data categories: May be exchanged where supported

Data suppliers:
all healthcare providers.

What is the European electronic health record exchange format?

EHDS Article 6:

Shorter version:

The EEHRxF is a set of technical specifications targeted at ensuring the interoperability of electronic health record systems used on the Union market

ical specifications for the **priority categories** of personal electronic health data
change format. Such format shall be commonly used, machine-readable and allow
pplications, devices and healthcare providers. The format should support transmission
ollowing elements:

tructures, such as data fields and data groups for the representation of clinical

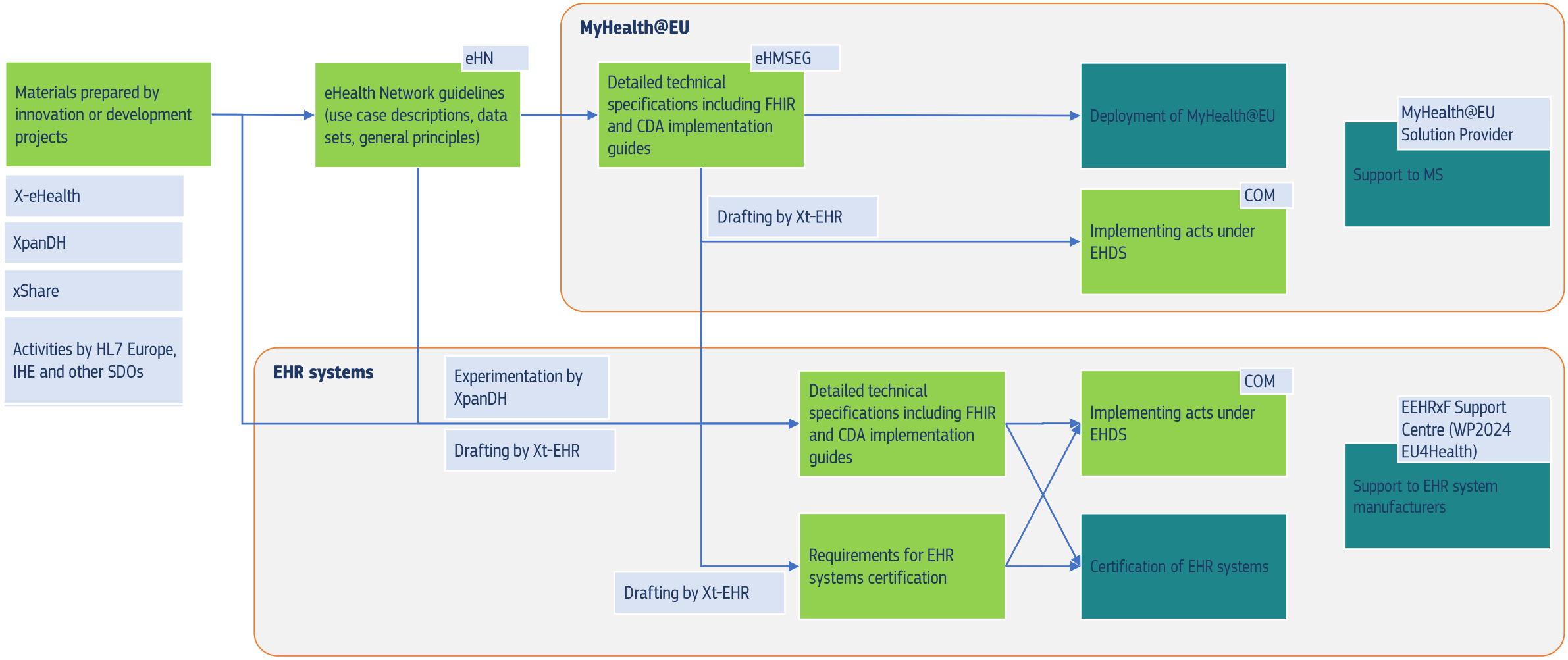
revisions of the healthcare coding systems and nomenclatures.

-1a. The Commission may, by means of implementing acts, lay down technical spec
additional categories of electronic health data referred to in Article 5(1), sub
examination procedure referred to in Article 68(2).

The European electronic health record exchange format is a powerful tool.

Common specifications (implementing acts under Article 23) are to further define the **requirements** for EHR systems regarding the support of the format (among other requirements).

Development of specifications in relevant EU-funded projects



Requirements for EHR systems

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

Interoperability component

- Provides capability to issue and accept data in EEHRxF as per Art. 6

Logging component

- Provides capability to generate the logs of access as per Art. 8f

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

EHDS in a Nutshell – Secondary Use

What for?

- Unleashing potential of the data economy in the health sector;
- Better evidence basis for regulatory activities and policy-making.

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure
- Data catalogues of available datasets
- Permits for data use, common safeguards

User journey

Data user

Data discovery — What health data exists to support my research?

Data access application — Can I use this data for my research project?

Health Data Holders

Health Data Access Body

Data preparation — Issue permit and make data ready for use, ensuring data quality and privacy

Data provision — Give access to Secure Processing Environment

Data User

Data use — Analyse and process data

Results output — Publish results, ensuring privacy and verifiability

Safeguards in secondary use

- Process for Health Data Access Bodies to vet applications (allowed and forbidden uses);
- Data minimisation and anonymisation / pseudonymisation
- Data provisioning in secure processing environments (access and export control, logging);
- Public transparency of applications, permits, results;
- Measures to protect intellectual property;
- Opt-out right for individuals.

Implementing the EHDS

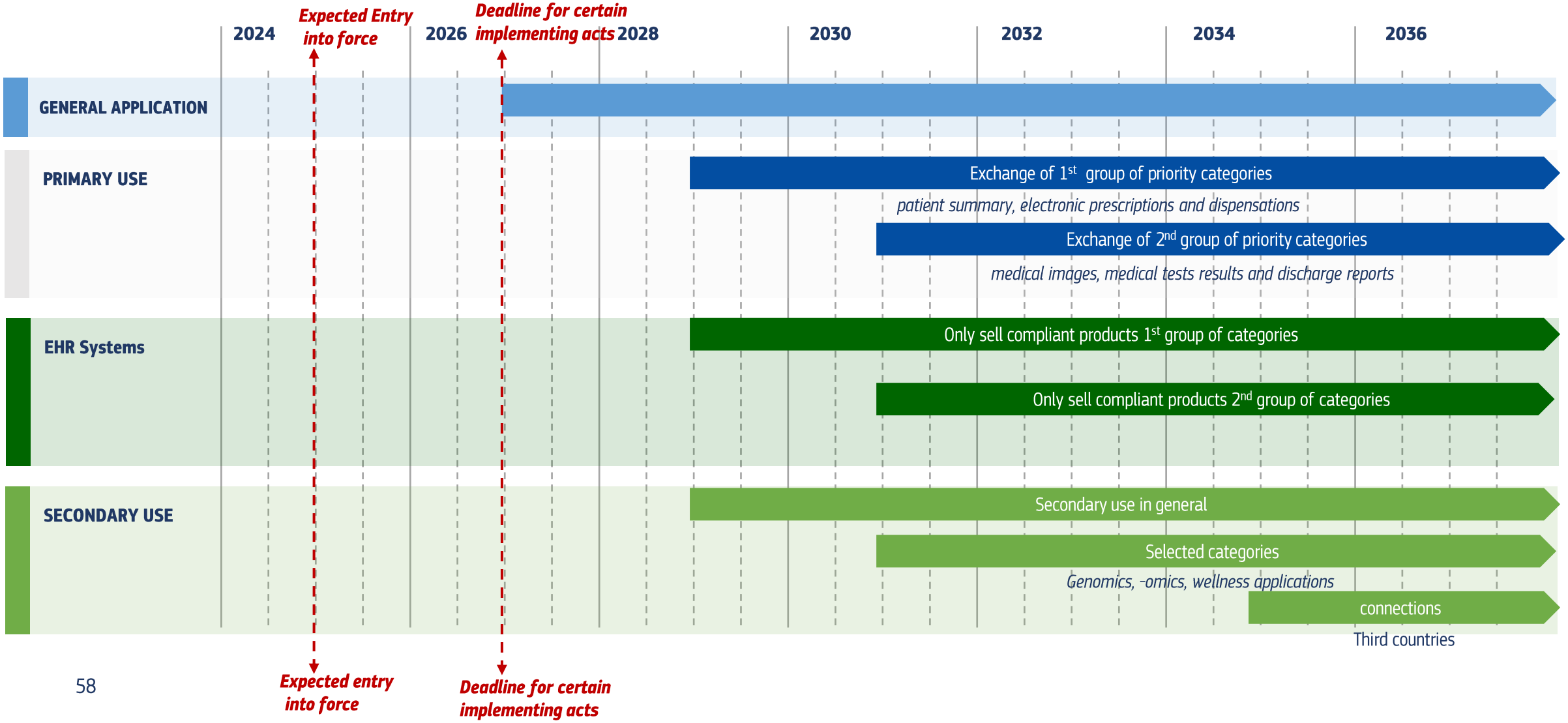
Next steps

- Adoption in corrigendum procedure: OJ publication expected late 2024
- Expected entry into application
  - General entry into application around EOY2026
  - Around EOY2028 for first batch of priority categories in primary use and large parts of secondary use
  - Around EOY2030 for remaining parts (e.g. discharge reports in primary)

Preparation

- Numerous projects and actions to provide input for specifications etc.: Xt-EHR, TEHDAS2, HealthData@EU Pilot, QUANTUM…
- Support with direct grants for Member States and capacity building support

EHDS – Overall timeline for application



Thank you

EU Digital Identity (EUDI) Regulation

To improve the effectiveness, accessibility, and trustworthiness of digital identities across Europe the co-legislators have adopted a new Regulation establishing the European Digital Identity Framework.

Strengthen the national eID system

Improve effectiveness and efficiency of mutual recognition of national eID schemes and make their notification mandatory for MS

- National eIDs as trust anchor
- Improve supply through mandatory Wallet & eID notification
- Mutual recognition procedure improved (peer reviews replaced by certification)

User Controlled Digital Identity (Personal Wallet)

European, secure “digital wallet”: trusted app on smartphone allowing storage and use (sole control of the user) of identity data, attributes, credentials, based on common standards

- User control (of wallet, data, support portability, ‘no tracking’)
- Link identity and credentials (drivers license, diploma)
- Wider set of use-cases across public and private

Private sector as provider of ‘identity linked services’

Private providers to offer digital identity-linked services by following the improved rules applicable for qualified trust services (anchored in national eIDs)

- Creation of new market for (verified) credentials, attestations
- Verification against authentic sources and eID linking
- Same legal effect of digital attributes as paper versions

Health data infrastructures, future European Digital Infrastructure Consortium (EDICs)

Making cancer imaging and genomics data accessible for research, healthcare and public health

Ms Aleksandra WESOLOWSKA,
Programme Officer - EU policies, Unit H.3., eHealth, Well-Being and Ageing?
DG CONNECT, European Commission

Mr Szymon BIELECKI,
Team Leader - EU policies, Unit H.3., eHealth, Well-Being and Ageing,
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1+ Million Genomes initiative

Szymon BIELECKI
European Commission, DG CNECT

Why collaborate on genomics?

Data and expertise

- Data dispersed across Europe – sequenced genomes
- Link, connect, protect, collaborate
- Secure access
- Scale effect

Research

- Better understanding of diseases
- Causes, risk factors, probabilities, cure

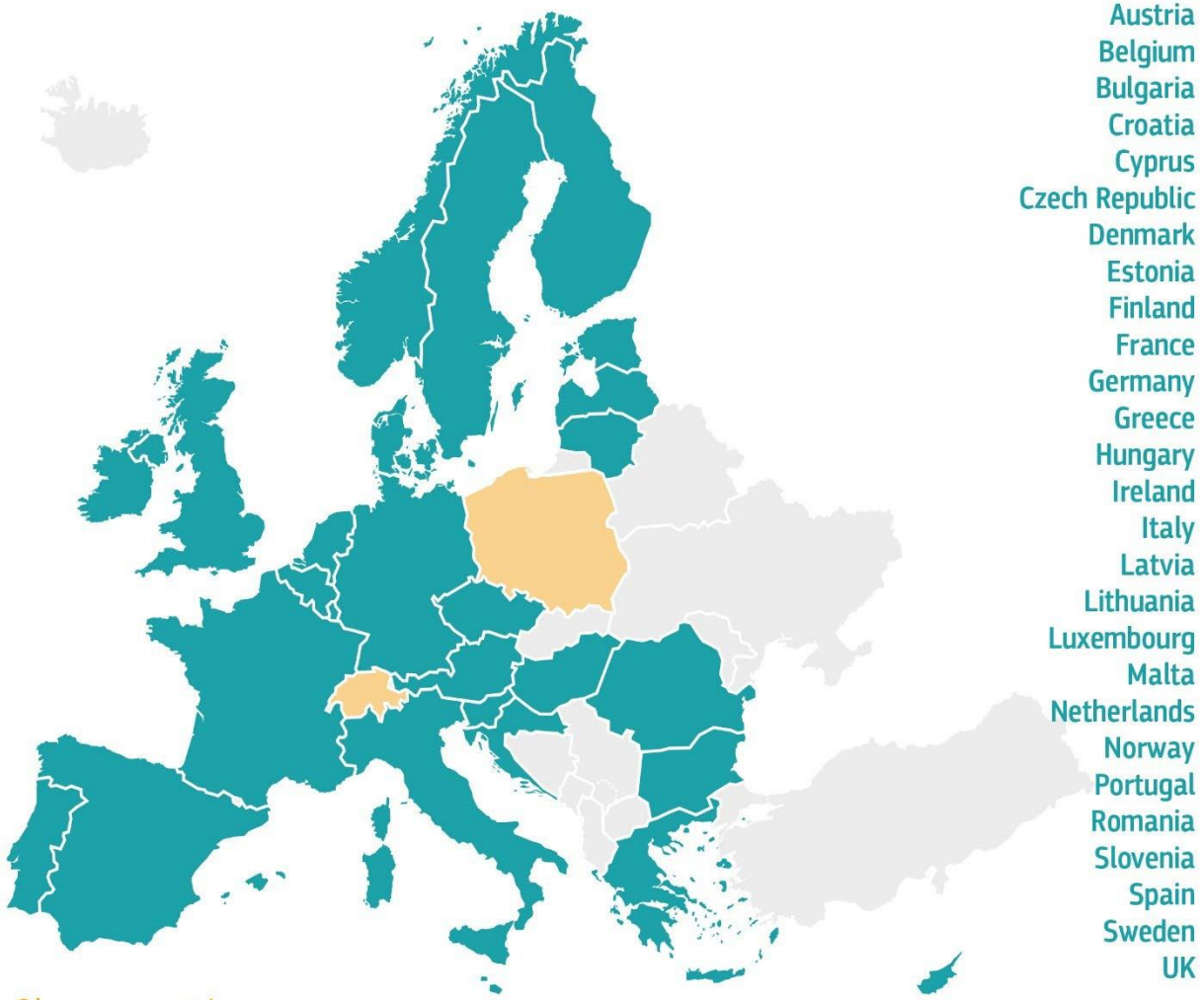
Healthcare

- Quicker diagnosis and treatment
- Personalised medicine
- Improved prevention programmes
- More efficient healthcare systems

Policy context

- 2018 Commission Communication on the digital transformation of health and care
- 2018 Member States' Declaration „Towards access to at least 1 milion sequenced genomes in the EU by 2022" 1+Million Genomes initiative (1+MG)
- 2020 European Data Strategy (European Health Data Space, data governance, AI, open data)
- Research, public health and digital agendas

Countries that have signed the 1+MG Declaration since 2018



Europe's Beating Cancer Plan (2021)

2.2. Making the most of data and digitalisation in cancer prevention and care

The digital transformation can bring significant benefits for the health sector. As much as 30% of the world's stored data are currently produced by health systems. But the health sector lags behind in exploiting this potential. It is a sector which is 'data-rich but information poor'[9].

Cancer care is one of the major disease areas that will benefit from the European Digital Strategy[10], thanks to better exploitation of real-world data[11] using powerful tools such as Artificial Intelligence (AI) and High-Performance Computing[12]. Despite this, barriers persist around interoperability[13], legal and ethical standards, governance, cybersecurity, technical requirements[14], and compliance with personal data protection rules[15].

Electronic health records are set to become crucial tools in cancer prevention and care[16]. They will ensure that clinical information is shared efficiently between oncologists, radiologists and surgeons, enhancing the patients' treatment and survival chances. Health records can also better capture the experiences and outcomes of oncology patients, painting a clearer picture than the 5% that participatein clinical trials. Combining health records, always in compliance with EU data protection rules, with other data sets, such as genomics, can provide even better insights into the efficacy of treatments and their optimisation[17].

Europe's Beating Cancer Plan seeks to make the most of the potential of data and digitalisation. The **European Health Data Space (EHDS)**, which will be proposed in 2021, will **enable cancer patients to securely access and share their health data in an integrated format in the electronic health records** between healthcare providers and across borders in the EU. The EHDS should give general practitioners and specialists access to patients' clinical data, ensuring that health and care delivery happens along the entire patient pathway, and will connect with the Knowledge Centre on Cancer to ensure that

5.4. Building on the promise of personalised medicine for cancer prevention, diagnosis and treatment

Every patient is different, and no cancer is the same. Preventing and treating cancer as effectively as possible calls for a personalised approach tailored to the characteristics of the patient and the disease. Personalised cancer medicines can significantly improve prevention, detection and prognosis for cancer patients and can reduce the risk of adverse effects. They should be part of the future of cancer medicines. In addition, the capacity to access genomic data cross-border in the EU will give researchers and clinicians the ability to analyse and compare patients' genetic and clinical information. This will help predict the potential development of cancers, detect the disease earlier, and decide on the most effective treatments.

The new **Partnership on Personalised Medicine**, due to be set up in 2023 and funded under Horizon Europe, will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice. As a preparatory action to the Partnership, the Commission will establish a **roadmap to personalised prevention**, identifying gaps in research and innovation, and will support an approach to map all known biological anomalies leading to cancer susceptibility, including hereditary cancers.

To support Member States in making the most of the rapid evolution of genomics in cancer prevention, diagnosis and treatment, in 2021 the Commission will launch, the **'Genomic for Public Health' project**. The project will complement the **1+ Million Genomes**

59 https://ec.europa.eu/digital-single-market/en/news/using-european-supercomputing-treat-coronavirus

Use cases

LOUISE

IMPROVING CANCER TREATMENT

BREAST CANCER

Louise has a long family history of breast cancer. One day, she heard on TV that mutations in the BReast CAncer genes *BRCA1* and *BRCA2* increase the risk of breast cancer by up to 80%. Although it turned out that she doesn't have mutations in these genes, her risk of developing the condition is still high due to her family history.

CANCER SCREENING

In order to detect early potential breast cancer, she started breast cancer screening at age 35, much earlier than the usual recommended routine screening. A few years later, Louise indeed developed breast cancer. To determine the most suitable type of treatment, she underwent a genomic test assessing the utility of chemotherapy versus other treatments in her case.

TREATMENT

Test results showed that Louise would not benefit much from chemotherapy, so doctors opted for a more effective personalised treatment, which also prevented her from experiencing the unpleasant side effects of chemotherapy.

Developments in the sequencing of cancer genomes are rapidly improving insights and predictive power of genomic tests on risk, prognosis and treatment of cancer. The 1+MG network will greatly increase the availability of this knowledge to oncologists, improving the choices for patients and the reducing over-treatment.

MARTIN

IMPROVING PROGNOSIS FOR RARE DISEASES

MICROCEPHALY

In 2015 Martin was born in Dublin, Ireland. Doctors recorded an abnormally small head and face, as well as a slow development rate. Genome sequencing identified many possible candidates for the genes that were causing his slow development. However, a precise diagnosis would be needed to start treatment.

EUROPEAN PLATFORM ON RARE DISEASES REGISTRATION

Launching a query through an EU federated platform that facilitates matching of cases with similar phenotypic and genotypic profiles allowed his doctors to find a second case in Spain with similar symptoms. Comparison of the sequencing results of the Irish and Spanish patients highlighted one mutation both had in common, which pointed to a defect that could be counteracted by supplying a specific metabolite.

Matching of cases with similar phenotypic and genotypic characteristics through an EU federated platform facilitates reaching an accurate diagnosis and treatment for rare disease patients with different backgrounds in separate countries. In this case this worked not only for Martin's condition but also for the Spanish patient.

JUSTYNA

PREVENTING COMMON AND COMPLEX DISEASES

POLYGENIC RISK SCORE

Justyna heard about the ongoing biobanking project in her country in the media, so she read more about the genetic risks of certain diseases. Her healthcare provider recommended a genomic analysis to estimate her Polygenic Risk Score (PRS), a test for most common diseases which was just introduced as a new clinical trial in the university hospital.

CORONARY ARTERY DISEASE

This genomic analysis showed that she has a PRS in the top 5% for Coronary Heart Disease (CAD). Drugs such as statins and other preventive measures lower the cholesterol levels in the blood and reduce the CAD risk, so her doctor suggested to initiate statin treatment and make some lifestyle changes.

PREVENTION

Now Justyna has to take statins. The genomic analysis also showed that one specific statin could increase her risk of muscle inflammation and should be avoided.
Justyna is now more aware of how to prevent CAD and make adjustments in her lifestyle, as well as receive the right treatment and regular check-ups, if needed.

Europe is currently developing PRS tests for early identification of risks factors for common diseases. The 1+MG project will yield genome sequences for many European citizens, in combination with phenotypic information, all collected with informed consent in biobanks across Europe. This will further the implementation of PRS testing in regular health care and will boost the availability of cheap prevention throughout Europe and elsewhere.

PABLO & PEDRO

TACKLING HIGH SENSITIVITIES TO INFECTIOUS DISEASES

COVID-19

Pablo (27 years old) develops severe COVID-19 symptoms. Shortly after, his brother Pedro (30 years old) is also tested positive. Both need to be treated in intensive care. The two brothers do not belong to any of the known risk groups, but their close family relationship suggests a genetic risk factor.

INFLUENCES

GENETIC

Genetic profiling of the brothers is undertaken and compared to other disease cohorts and population biobank resources. It turns out that Pablo and Pedro are carriers of a rare genetic mutation in TLR7 (Toll Like Receptor 7). This gene on the X chromosome regulates the interferon level as a defensive response to viruses. Based on this finding, Pablo and Pedro receive a specific treatment to restore the natural capacity of their immune system to fight the virus.

DATABANK NETWORK

Imagine we would have the EU federated genomic data network of 1+MG in place offering European clinicians the possibility to receive alerts when they encounter patients with similar characteristics. Patients' increased susceptibility to life threatening conditions caused by an infectious disease such as COVID-19 could be rapidly discovered and the necessary treatment adapted and personalised.

1+MG Roadmap 2023 - 2027

IMPLEMENTATION TRACKS

1- Developing and maintaining the 1+MG Framework

2- Establishing and expanding the 1+MG data infrastructure

3- Generating accessible 1+MG-ready data

4- Promoting national engagement, contributions and alignment

5- Aligning with the European Health Data Space and other European initiatives

1+MG

Personalised Medicine

USE CASES

- Synthetic data
- Genome of Europe
- Rare Diseases
- Cancer
- Complex diseases
- Infectious diseases

European Genomic Data Infrastructure

Secure cross-border access to genomic and health data, for research, personalised healthcare and public health policy

2018 2019 2020 2021 2022 2023 2024 2025 2026 2027

Design & Testing

1+MG Declaration

European Commission
Horizon 2020
European Union funding for Research & Innovation

B Beyond 1MG one Million Genomes

Scale-up & Sustainability

European Genomic Data Infrastructure

The European '1+Million Genomes' (1+MG) initiative facilitates signatory countries to realise a practice of personalised medicine and health, based upon a shared 'framework' and the infrastructure to safely access and integrate high quality genomic data and other health data across borders. *[1+MG Roadmap 2023-2027]*

Population Genomics

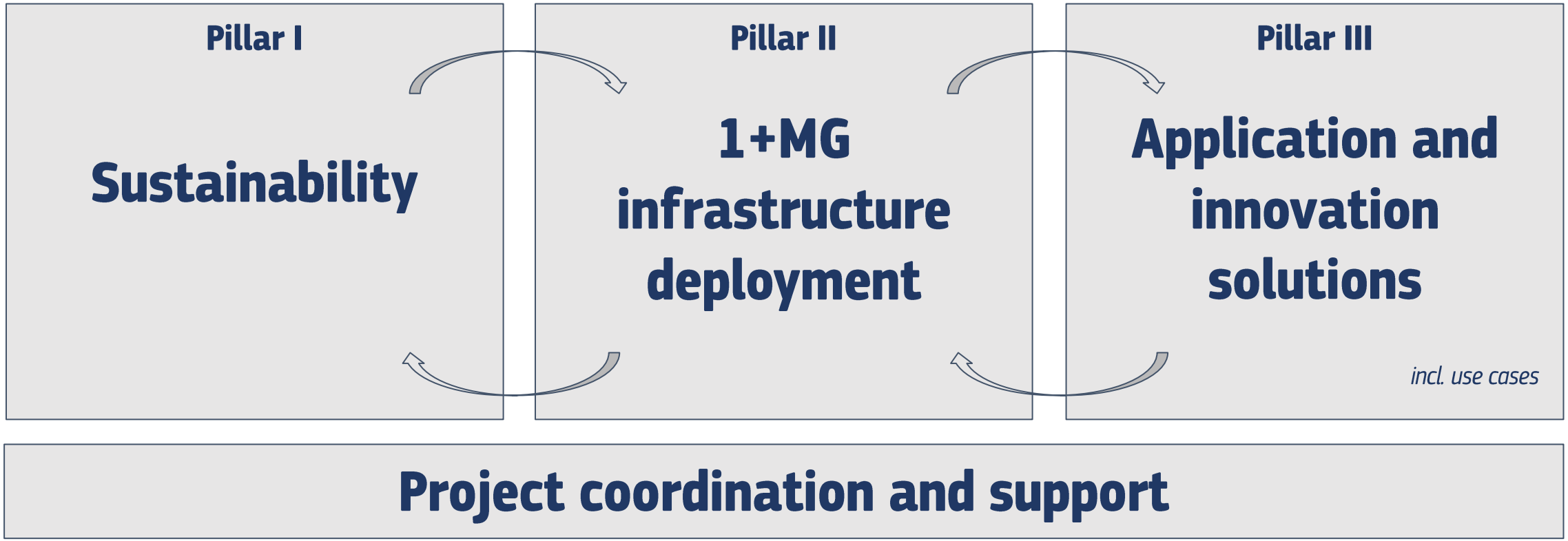
Genome of Europe

EDIC, healthcare uptake

(forthcoming CSA)

European Genomic Data Infrastructure

- **54 beneficiaries: 20 Member States, 2 research infrastructures**
- **coordination: EMBL/Elixir**
- **6 national nodes operational by 2024, 9 more by 2026**
- **numerous other projects linked in**

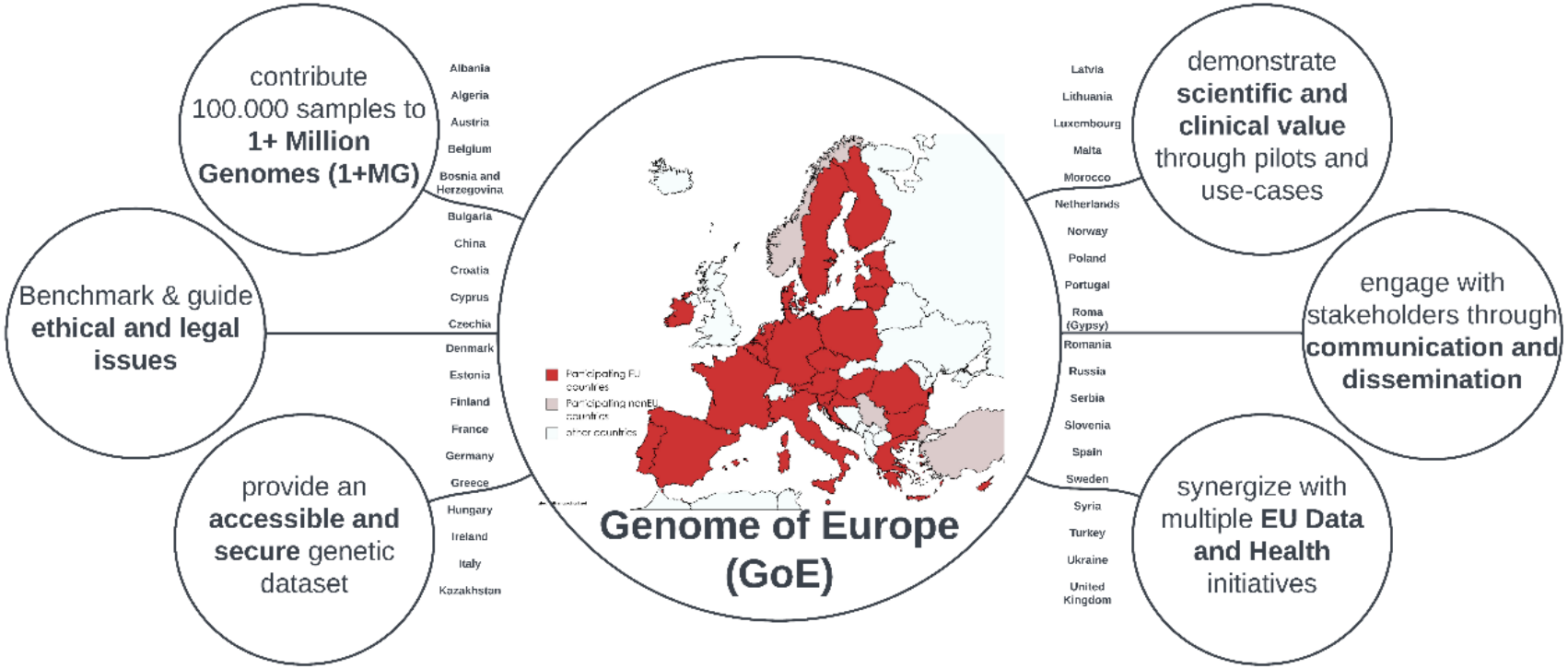


- Project launched on 1/11/2022 for a duration of 4 years
- 40M€ budget with 50% EU share (DEP)

The Genome of Europe: GoE project

- 51 participants: 26 EU + 3 non-EU countries
- Coordination: ErasmusMC
- Duration: 42 months

- Budget EUR 45m: EUR 20m (DEP) + EUR 25m from participants
- GA under preparation

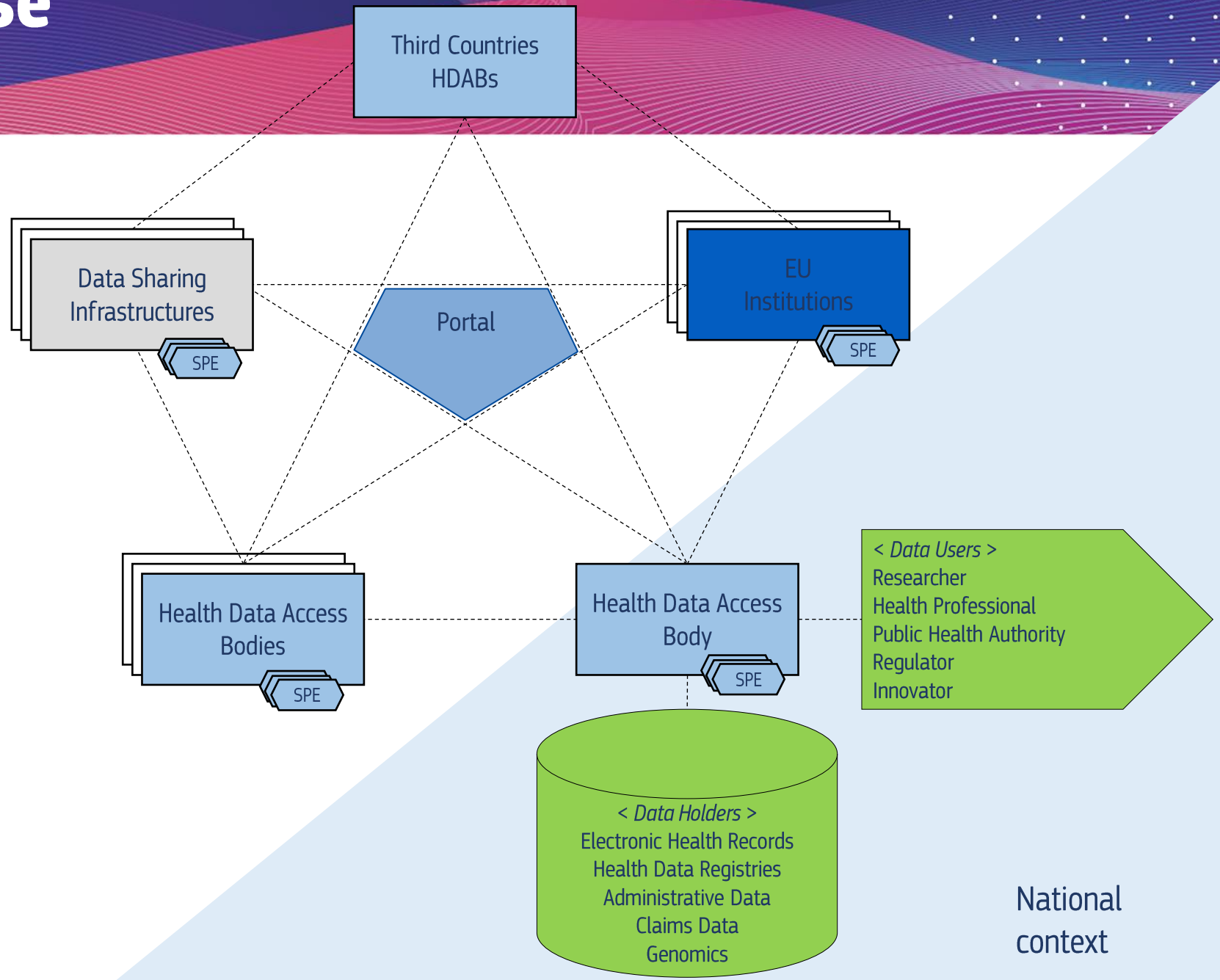


FOCUS

- ✓ **100.000** WGS
- ✓ General citizens as "**normal control population**"
- ✓ Overview of **genetic variation across Europe**
- ✓ Population composition by country size and ancestral background

EHDS secondary use infrastructure

(HealthData@EU)



Central support services
provided by EC

National data management services
provided by authorised participants

SPE
Secure Processing Environments

Local services
provided by/to local partners

European Digital Infrastructure Consortia (EDIC)

2030 DIGITAL DECADE

- Concept strongly influenced by the success of **European Research Infrastructure Consortia (ERICs)**. Advantages: **speedy** establishment and **flexible** implementation.
- Purpose: **establish and operate a multi-country project** enabling infrastructure deployment & operation combined with long-term sustainability.
- Form: **a legal entity** set up by a decision of the Commission upon a request of a group of MS.
- Legal personality and full legal capacity recognised in all MS, liable for its own debts
- **At least three Member States as members** and **open for new MS** as members; the **internal structure** will be flexible and defined in the statutes by members.
- The main sources of financing for the EDIC would be **commitments** of the EDIC members and grants from the directly managed **EU funding instruments.**
- In particular, EDIC will be able to apply for funding from all centrally-managed EU programmes (notably: DEP, CEF, Horizon Europe), RRF and funds under shared management.

Genome EDIC state-of-play

- Legal entity to offer secure access to data to authorised users (e.g. clinicians, researchers, innovators) for genomics **research**, more precise, faster, personalised **diagnostics/treatment**, and improved **public health** measures
- EDIC will operate the technical infrastructure established by the GDI project in accordance with an agreed data governance
- General expression of interest by 19 MS so far
- Task Force working on the statutes and application: **LU (host)**, DK, BE, CZ, EE, ES, FI, FR, RO, SE

Thank you very much for your attention!

More info: European '1+ Million Genomes' Initiative (europa.eu)

European Genomic Data Infrastructure (GDI) project (onemilliongenomes.eu)

Contact: Szymon.Bielecki@ec.europa.eu

European Cancer Imaging Initiative
#euCancerImaging

Aleksandra Wesolowska

European Commssion, DG CNECT

EUROPEAN CANCER IMAGING INITIATIVE

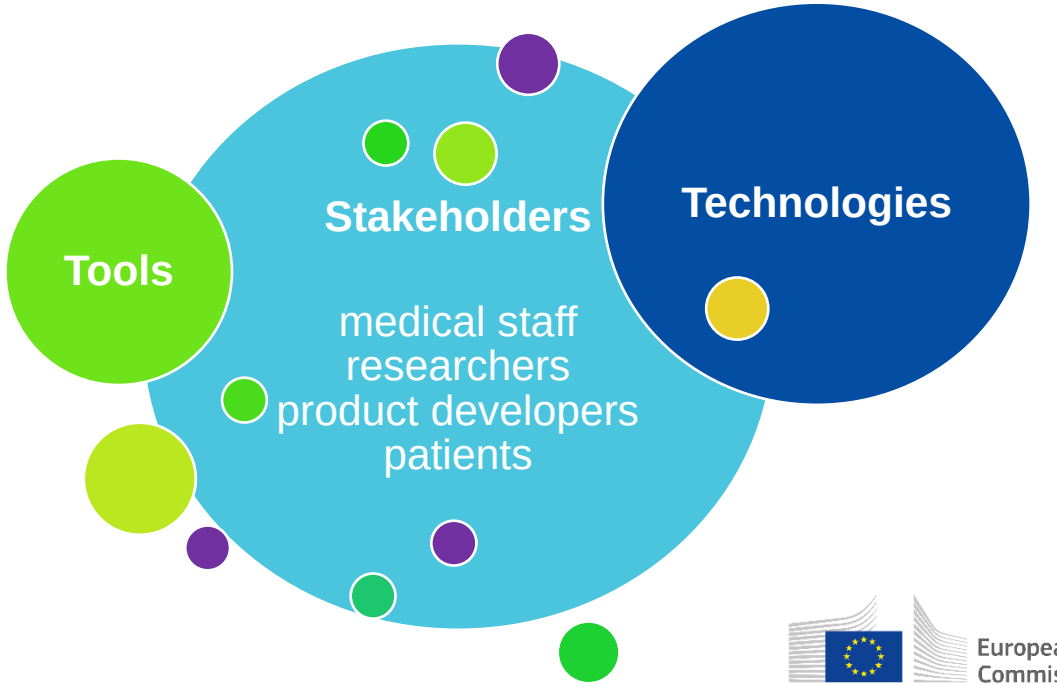
Flagship initiative in the Europe's Beating Cancer Plan

- Builds on substantial research efforts and EU funding on **AI and cancer imaging** by leading European researchers

- **AI4HI Cluster of H2020 projects**

chAImeleon EUCAN IMAGE ProCAncer-I AIncisive PRIMAGE Medical Imaging Artificial Intelligence Childhood cancer research

- Overall aim: **foster innovation and deployment of digital technologies in cancer treatment and care**



European Commission

Cancer Image Europe

www.cancerimage.eu

- Pan-European digital infrastructure for cancer images and related clinical data for AI development and testing
  - Deployed by **EUCAIM project**
  - **DIGITAL Europe programme**
    (50% EU funding; 50% Member State funding)
  - Radiological and nuclear medicine images (MRI, CT, mammography, PET…) and related clinical information
  - Standardised and harmonised, ready to be used to develop Artificial Intelligence (AI) tools for Precision Medicine
  - Users: **researchers**, **innovators** and **clinicians**

European Commission

EUROPEAN CANCER IMAGING INITIATIVE

What can we expect from EUCAIM?

- Mid-term **Atlas** of >60 million annotated cancer images and >100,000 patients (Atlas).
- A continuously growing Infrastructure based on observational studies at hospitals, (**real world data from Hospital Data Warehouses and Screening programmes**).
- An **AI-platform** to develop **reproducible image-based AI models in oncology**.
- **Impact on Clinical Pathways** in Radiology and Oncology: growing evidence-based use of imaging biomarkers and imaging panels identifying the right treatment to the right patients, in many different oncologic situations.

European Commission
EUROPEAN HEALTH DATA SPACE
#EUDigitalHealth

European Commission
EU Health Union:
Europe's Beating Cancer Plan
#EUCancerPlan

European Commission

Project targets

- **KPI1**: Number of hospitals and imaging data repositories linked to the central hub. The project starts with 21 clinical sites from 12 countries and aims to have **at least 30 distributed data providers from 15 countries** by the end of 2026.

- **KPI2**: Both common (such as breast, lung, prostate, colorectal, lymphoma, multiple myeloma) and rare (e.g., ovarian, paediatric) cancers will be included with anonymized images and annotations. **More than 100,000 cases are expected to be included.**

- **KPI3:** Number of researchers and health care professionals and innovators using the platform in operational mode. **At least 300 from 15 countries by the end of 2026.**

Start with **21 clinical sites** from **12 countries**

Connect **≥30 data providers** from ≥15 countries by 2026

EUROPEAN CANCER IMAGING INITIATIVE

Accelerating the development of AI-based cancer management solutions and other data-driven cancer research activities, enabling and empowering scientific breakthroughs that will shape the future of cancer diagnosis and treatment

EUCAIM
CANCER IMAGE EUROPE

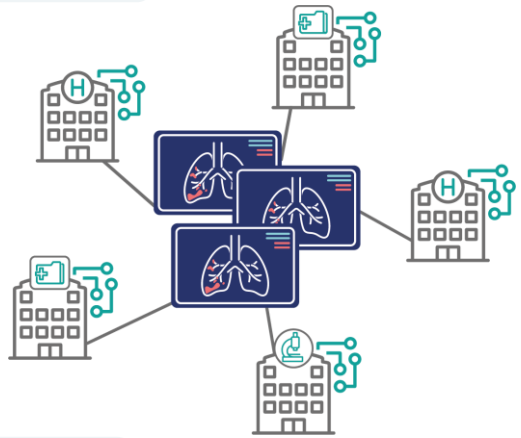
Cancer Image Europe Infrastructure Status as in June 2024

8 cancer types
breast, colon, lung, prostate, rectum, liver, glioma, neuroblastoma

Central storage for de-identified data

EUCAIM Dashboard
Version 1 released

Participation rules defined
three levels of compliance with EUCAIM's data model defined



Federation Core Services
Version 1 released

Central Hub in Operation for Internal Clinical Validation

AI experimentation platform
where dockerized AI tools can be deployed

Central Core Infrastructure Services
Version 1 released

Hyperontology (v0.2 beta)
with OMOP and FHIR integrations

Searchable public catalogue of 46 datasets
(approx. 35 000 subjects)*
from the AI4HI network of EU-funded projects

Federated search and first prototype of **federated learning**

EUCAIM project space
set at OpenEBench

* *catalogue links to data providers, where access to data can be requested*

Available at **cancerimage.eu**

European Commission

EUROPEAN CANCER IMAGING INITIATIVE

TIMELINE

2023
Design completed
- Requirements analysis
- Design
- Collaboration mechanisms
- Early release of the Data Federation Framework

2024
First version of platform
- Platform validated and populated for external production
- Data providers connected
- Prototype for federated learning
- Benchmarking platform

2025
Final release of platform
- Federated learning
- Final version of tools and services
- Federation of new cancer images databases through open calls
- Implementation of clinical use cases

2026
Full operation of federated repository
- Integration with other data infrastructures
- Piloting of the business model
- Legal and operational model finalized

2027
Expansion

Testing – experimentation – benchmarking – interoperability – ethics, trust, security – stakeholder engagement

European Commission

Sustainability – towards EUCAIM EDIC

European federated data infrastructure for secure access to quality cancer imaging data and related clinical information for the development and benchmarking of AI-based cancer management tools towards personalised medicine

Accelerator and facilitator for:

- Researchers to better understand, diagnose and fight against cancer
- National and regional administrations to design and run Cancer Screening programmes
- Researchers, industry and clinicians to design and run observational studies and build reproducible image-based decision support models in oncology
- Data holders to comply with the GDPR (and upcoming European Health Data Space Regulation)

A dedicated **EUCAIM EDIC Working Group** has been established

countries participating in the WG: ***Spain***, ***Italy***, ***Greece***, ***France***, ***Latvia***, ***Lithuania***, ***Czechia***, ***Portugal***, ***Norway***, ***Croatia***, *Cyprus*, Sweden*, Poland*, The Netherlands*, Germany**

Questions & Answers

Conclusion

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CONNECT UNIVERSITY