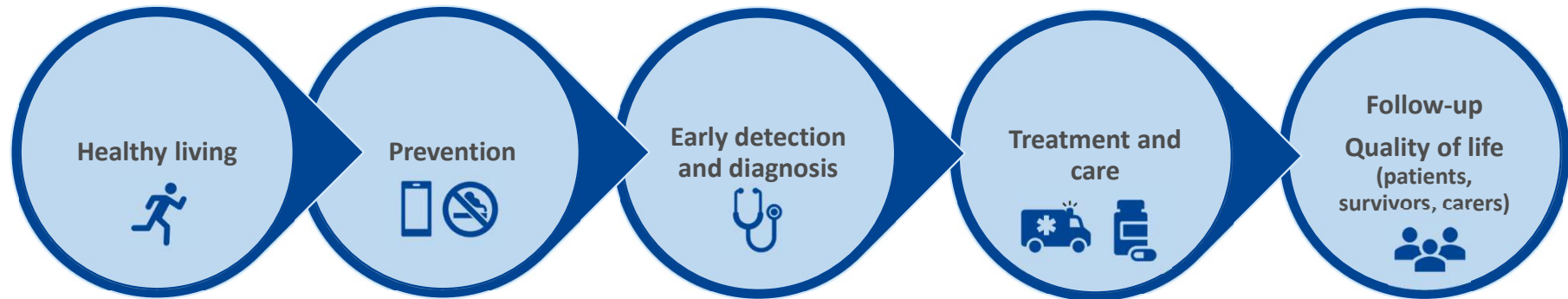# European Health Data Space

Conférence luxembourgeoise sur la documentation et classification des séjours hospitaliers, 22/02/23

Marco Marsella, Head of Unit
CNECT.H3 eHealth, well-being and ageing
European Commission

Digital technologies driving innovation in health
Across the care pathway

Healthy living

Prevention

Early detection and diagnosis

Treatment and care

Follow-up
Quality of life
(patients, survivors, carers)

- ✓ Citizen empowerment through access to own health data
- ✓ mHealth apps
- ✓ COVID-19 contact tracing apps / EU Digital COVID-19 Certificate

- ✓ Diagnostic tools and AI applications
- ✓ Robotics
- ✓ 1+ Million Genomes Initiative
- ✓ European Cancer Imaging Initiative
- ✓ Virtual twins

- ✓ Virtual twins
- ✓ AI and data analytics solutions for clinical research and decision making
- ✓ Robotics
- ✓ mHealth Apps

- ✓ AI solutions to monitor health status and quality of life after treatment

➢ **Societal impact – cost efficiencies – long healthy lives – personalised care – patient empowerment**
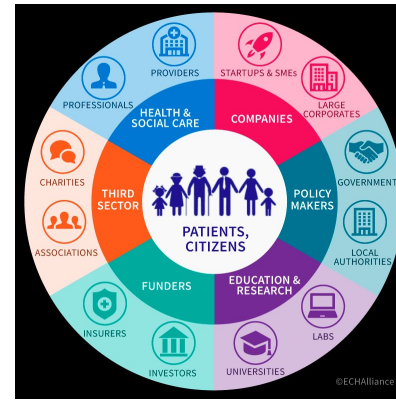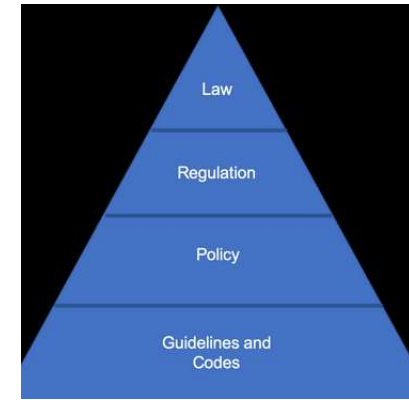
Transformative Digital Health Technologies

| DATA | (Digital) Infrastructure harmonisation | Ecosystem & coordination | Legal Framework & Policies |

The European data strategy to make the European Union a leader in a data-driven society

The European Strategy for data at a glance

The **European Strategy for data** (2020) aims to make the EU a leader in a data-driven society.

The **Data Governance Act** (2020) facilitates data sharing across sectors and Member States.
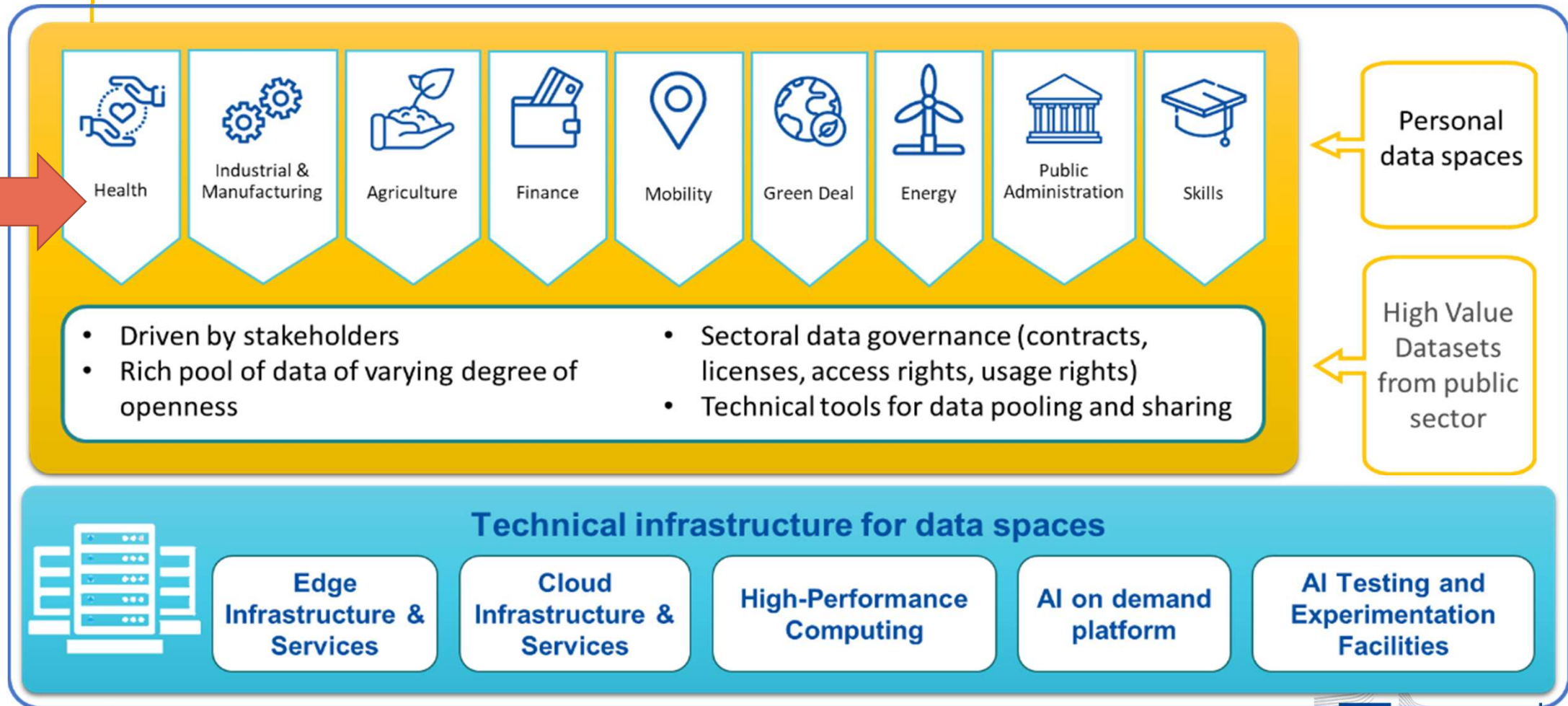
The **Data Act** (2022) clarifies who can create value from data.

Ten **European common data spaces**, ranging from industry to mobility, from European Green Deal to energy and health.

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Common European Data Spaces, including for Health

Health	Industrial & Manufacturing	Agriculture	Finance	Mobility	Green Deal	Energy	Public Administration	Skills

- Driven by stakeholders
- Rich pool of data of varying degree of openness

- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Personal data spaces

High Value Datasets from public sector

Technical infrastructure for data spaces

Edge Infrastructure & Services	Cloud Infrastructure & Services	High-Performance Computing	AI on demand platform	AI Testing and Experimentation Facilities

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# Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower <u>individuals to access and control</u> their personal health data
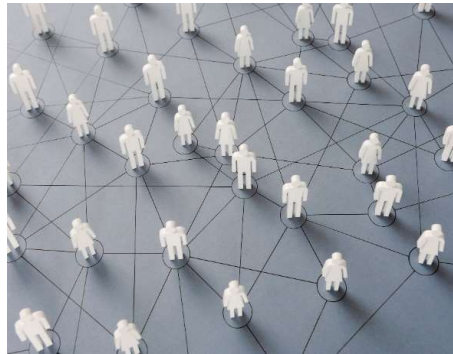
<u>Ensure a consistent framework</u> for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by <u>fostering a genuine single market</u> for digital health services and products (EHR systems)

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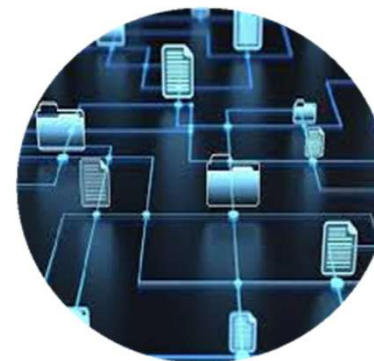
European Health Data Space (EHDS)

▶ OBJECTIVES

Effective use of health data

▶ SCOPE & EXPECTED IMPACT

Use of health data (primary, MyHealth@EU)	• Empower individuals to control their data • Standardization and mandatory certification of EHR systems • Voluntary labelling of wellness apps • European Electronic Health Record Exchange Format	→	Single market for health data, data protection, free movement of people, digital goods and services
Re-use of health data (secondary, HealthData@EU)	• Health data access bodies • Purposes for use and forbidden use • Data permits, secure environments, no identification	→	Facilitated Research & Innovation Better Policy Making

▶ MEANS

Legal / Governance	Quality of data	Infrastructure	Capacity building/digitalisation (MFF)

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The scope of EHDS (*Article 1*)

Strengthens the rights of individuals in relation to greater control over their electronic health data:

access in electronic form immediately, without any cost; to share their data with health professionals nationally or cross-border; to add information, rectify errors, restrict access and obtain information on what health professional accessed their data, a right to health data issued and accepted in a common European format, to strengthen interoperability. Designation of digital health authorities, to uphold the rights

Rules for electronic health record systems

- Mandatory requirements for interoperability and security + CE marking

Rules and mechanisms supporting the secondary use of electronic health data

- Legal base for data made accessible
- Provisions for compulsory health data sharing
- Designation of health data access bodies

Mandatory cross-border infrastructure for primary and secondary use of health data

- cross-border digital infrastructure for the exchange of health data **MyHealth@EU**
- **new decentralised EU-infrastructure** for secondary use **(HealthData@EU)**

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EHDS – benefits for users

Empower citizens to have control over their health data

Assist policy makers and regulators in accessing relevant health data

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Health data from apps and medical devices

Health data in registries

Electronic health records

Facilitate access to health data for innovators in industry

Better health policy, greater opportunities for research and innovation

Enable healthcare professionals to have access to relevant health data

Grant access to health data for researchers

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

AI Act

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

Medical Device Regulation

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

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Cross-border Infrastructure & Ecosystems

MyHealth@EU: Cross-border infrastructure for healthcare provision

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

Doctor access to foreign citizen Patient Summary

Patient Summary

Used while traveling abroad and being in necessity of consulting a doctor in that country.

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) and overcome linguistic barriers.

eHealth Network Patient Summary guidelines, including minimum dataset

European Commission

MyHealth@EU: Cross-border infrastructure for healthcare provision

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

Patients access to ePrescriptions abroad

Electronic prescription in Europe – a Finnish patient purchasing medication in a pharmacy aboard
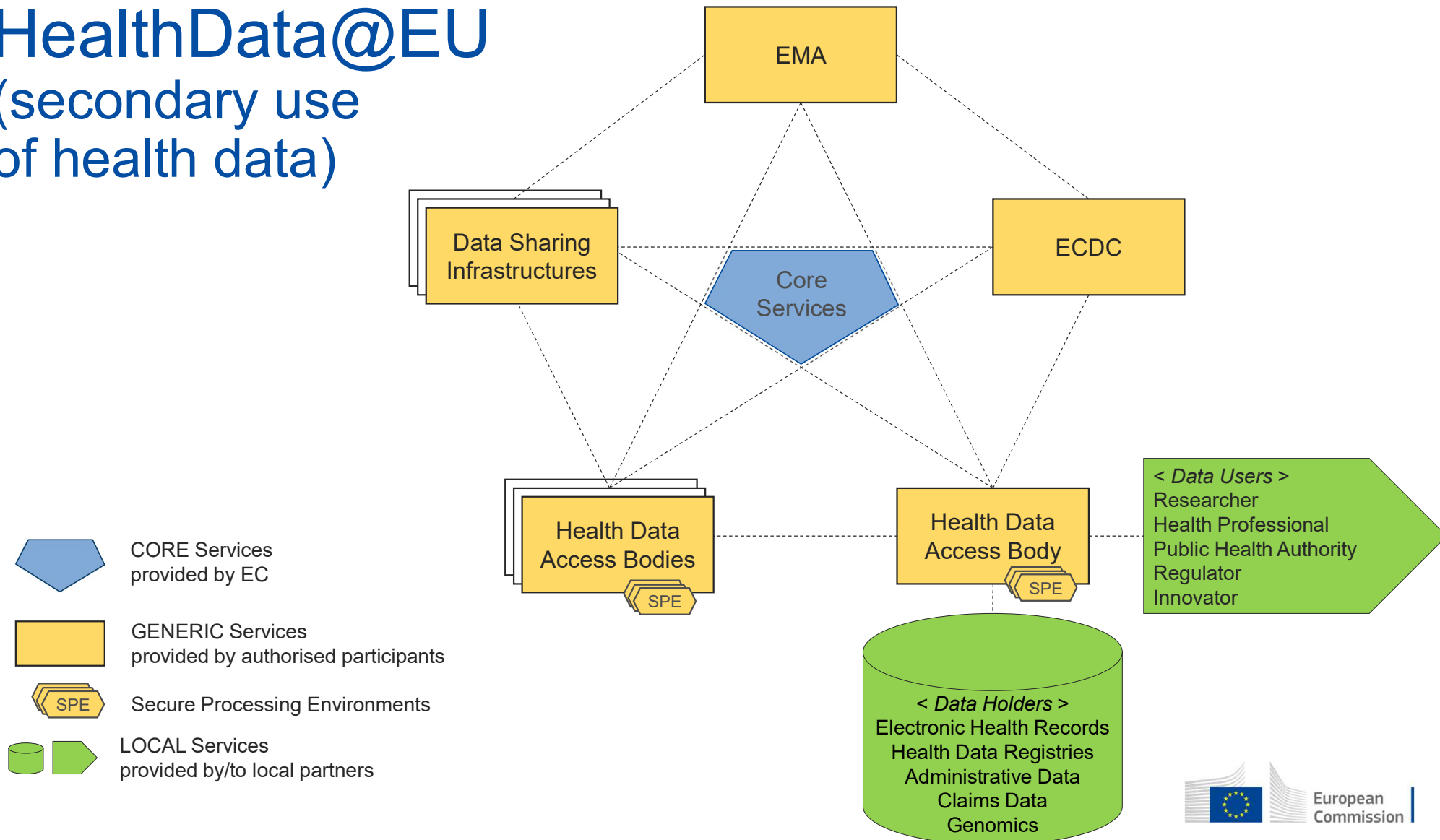
ePrescription

allows citizens in Europe to retrieve their medication in a pharmacy located in another European country without having to bring the printed prescription and without being concerned about the language barrier.

eHealth Network ePrescriptions and eDispensation guidelines

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HealthData@EU
(secondary use of health data)

EMA

Data Sharing Infrastructures

Core Services

ECDC

Health Data Access Bodies

Health Data Access Body

SPE

SPE

< Data Users >
Researcher
Health Professional
Public Health Authority
Regulator
Innovator

< Data Holders >
Electronic Health Records
Health Data Registries
Administrative Data
Claims Data
Genomics

Legend:

CORE Services
provided by EC

GENERIC Services
provided by authorised participants

SPE — Secure Processing Environments

LOCAL Services
provided by/to local partners

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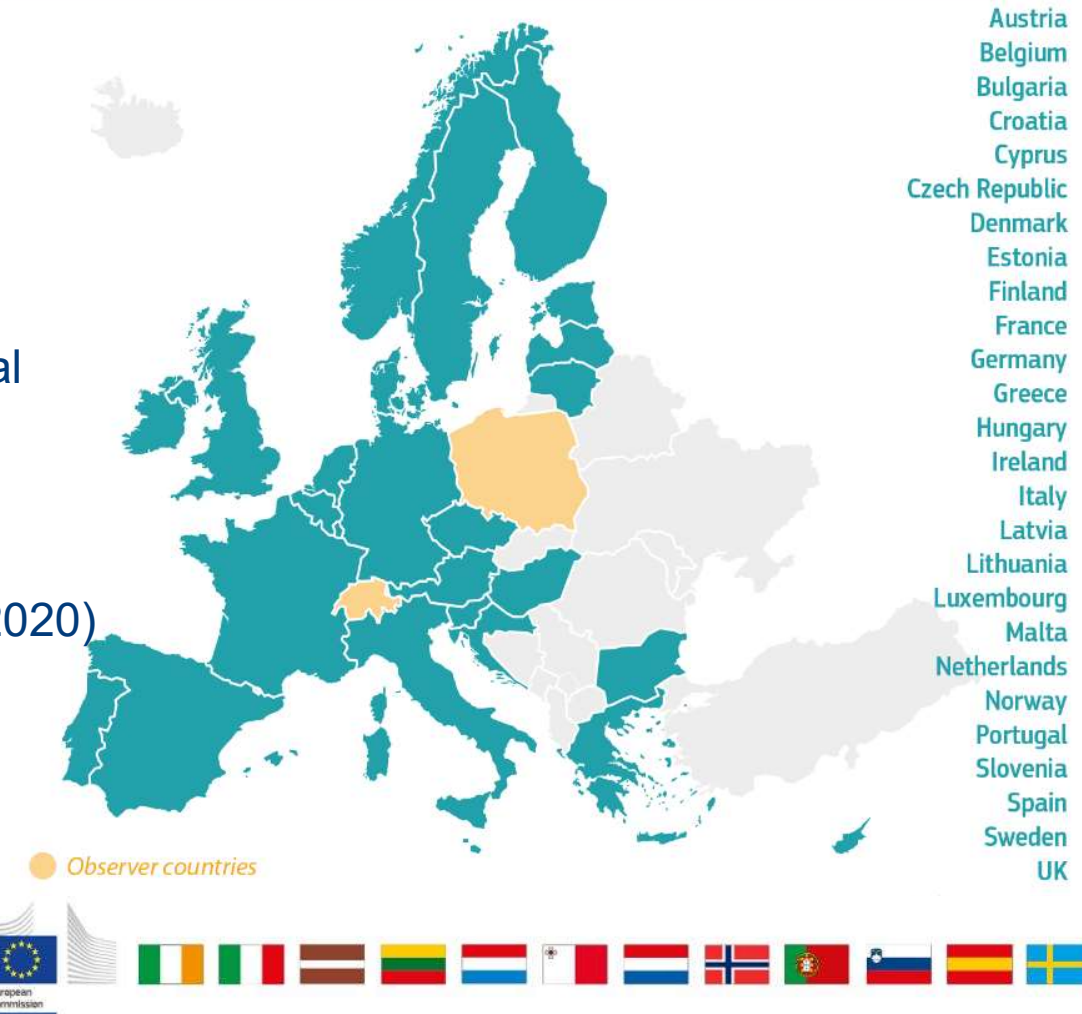
1+ Million Genomes EU initiative (1+MG)

- 2018 Member States' Declaration signed by 26 countries by now

- For research, healthcare and public health

- Strategic overview: 1+MG Group (governmental representatives)

- Expert work: 12 working groups

- Coordination support via the B1MG project (H2020)

- Data infrastructure via the GDI project (DEP)

- Genome of Europe – coordinated sequencing

Countries that have signed the 1+MG Declaration since 2018

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Norway
Portugal
Slovenia
Spain
Sweden
UK

● Observer countries

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

Sustainability	1+MG infrastructure deployment	Application and innovation solutions
Led by Luxembourg and Spain		

Project coordination and support
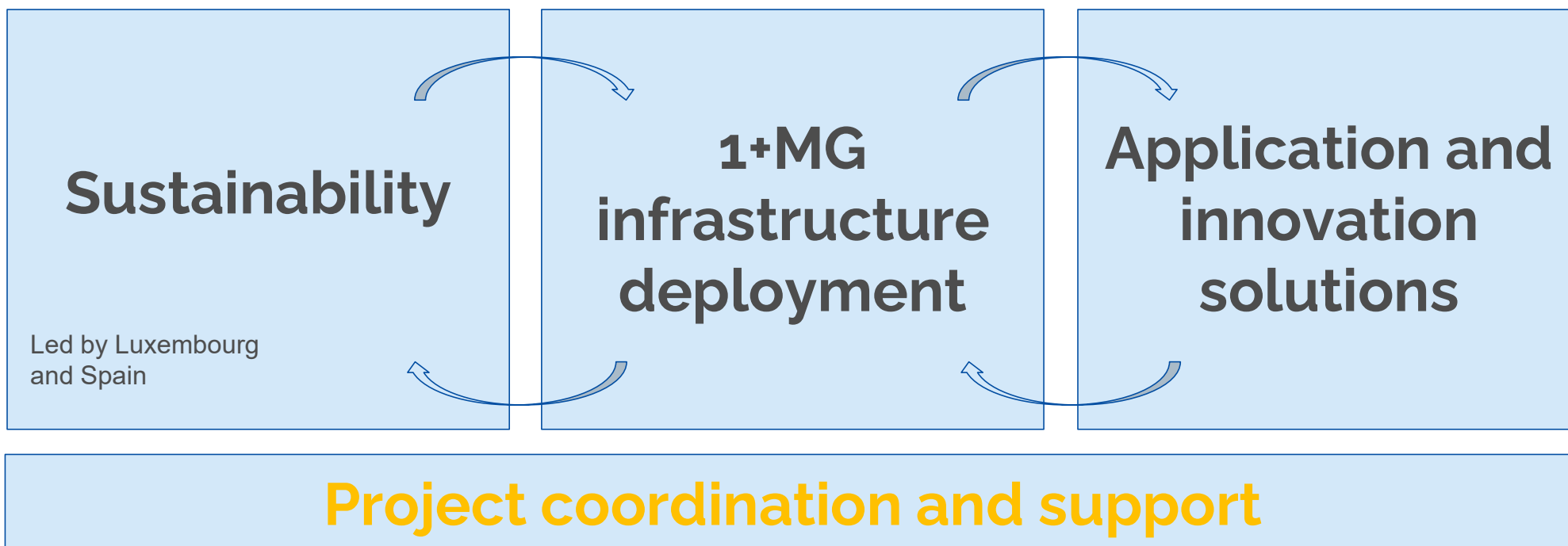
➢ Plateforme nationale d'échange des données (PNED) – *beneficiary*
➢ Ministry of Research – *associated partner*

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EUROPEAN CANCER IMAGING
INITIATIVE

An EU state of the art platform to support the piloting and development of new computer-aided tools to improve personalised medicine and innovative solutions, demonstrating the power of Artificial Intelligence and digital technologies to beat cancer
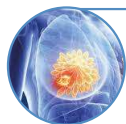
Vision and Mission of this Initiative

Deploy a pan-European **federated infrastructure** to power up AI & Imaging to beat cancer

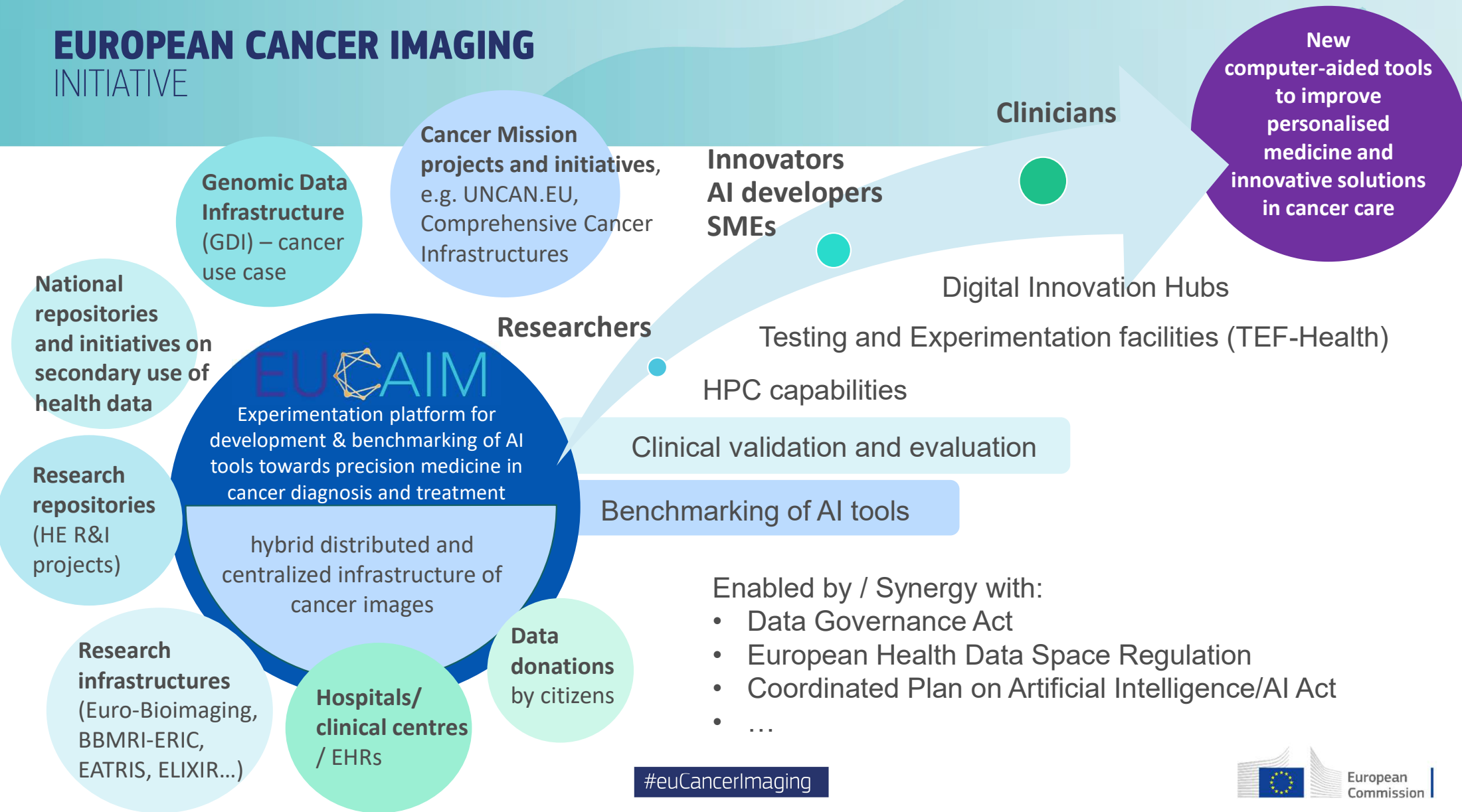Provide a **Research Platform** for the development & benchmarking of AI tools toward Precision Medicine

Address the fragmentation of the existing cancer image repositories by building a **distributed Atlas of Cancer Images** *(>60M cancer images)*

Create a **Federated Datawarehouse** approach for deploying Observational Studies and populate the centralized Image Repository
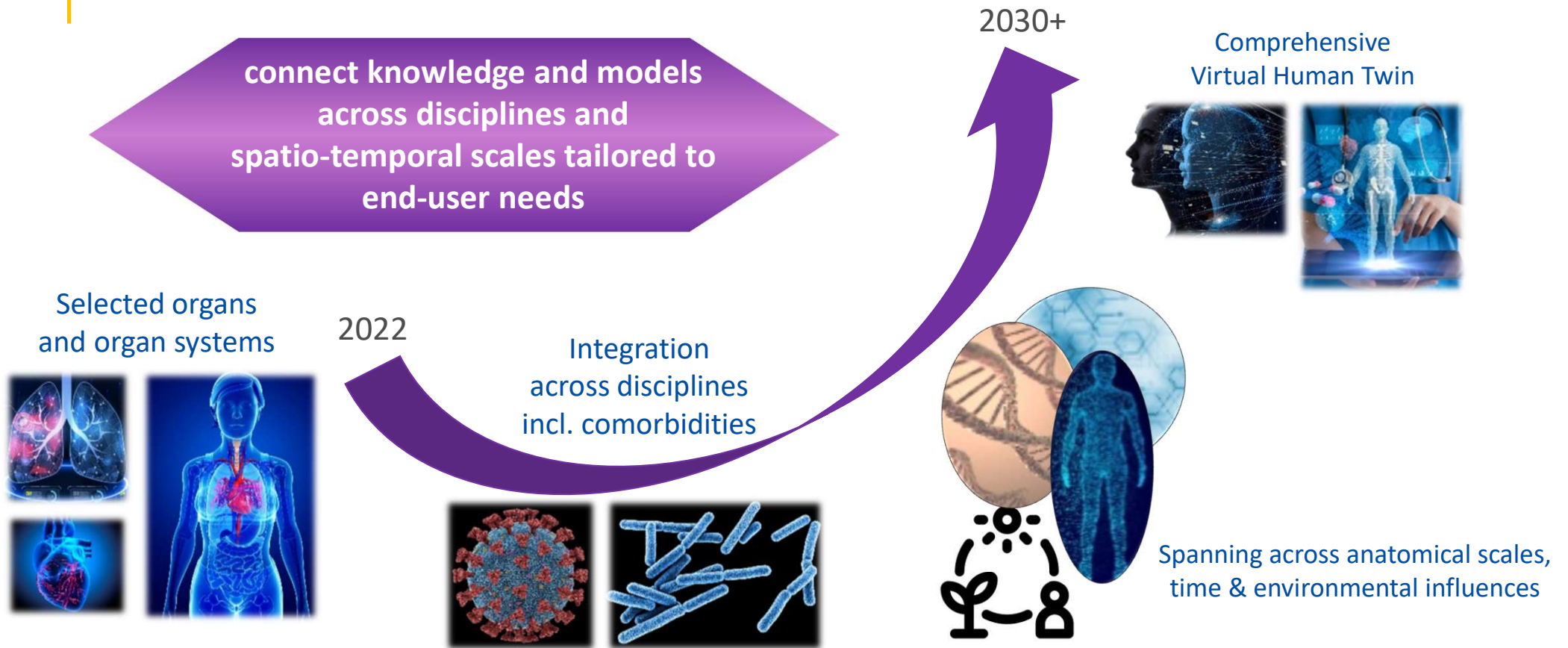
#euCancerImaging

European Commission

EUROPEAN CANCER IMAGING
INITIATIVE

Genomic Data Infrastructure (GDI) – cancer use case

Cancer Mission projects and initiatives, e.g. UNCAN.EU, Comprehensive Cancer Infrastructures

Innovators AI developers SMEs

Clinicians

New computer-aided tools to improve personalised medicine and innovative solutions in cancer care

National repositories and initiatives on secondary use of health data

Researchers

EU AIM

Experimentation platform for development & benchmarking of AI tools towards precision medicine in cancer diagnosis and treatment

hybrid distributed and centralized infrastructure of cancer images

Digital Innovation Hubs

Testing and Experimentation facilities (TEF-Health)

HPC capabilities

Clinical validation and evaluation

Benchmarking of AI tools

Research repositories (HE R&I projects)

Research infrastructures (Euro-Bioimaging, BBMRI-ERIC, EATRIS, ELIXIR...)

Hospitals/ clinical centres / EHRs

Data donations by citizens

Enabled by / Synergy with:
- Data Governance Act
- European Health Data Space Regulation
- Coordinated Plan on Artificial Intelligence/AI Act
- …

#euCancerImaging

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Towards Virtual Twin(s) of the human

connect knowledge and models across disciplines and spatio-temporal scales tailored to end-user needs

2030+

Comprehensive Virtual Human Twin

Selected organs and organ systems

2022

Integration across disciplines incl. comorbidities

Spanning across anatomical scales, time & environmental influences

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An inclusive ecosystem
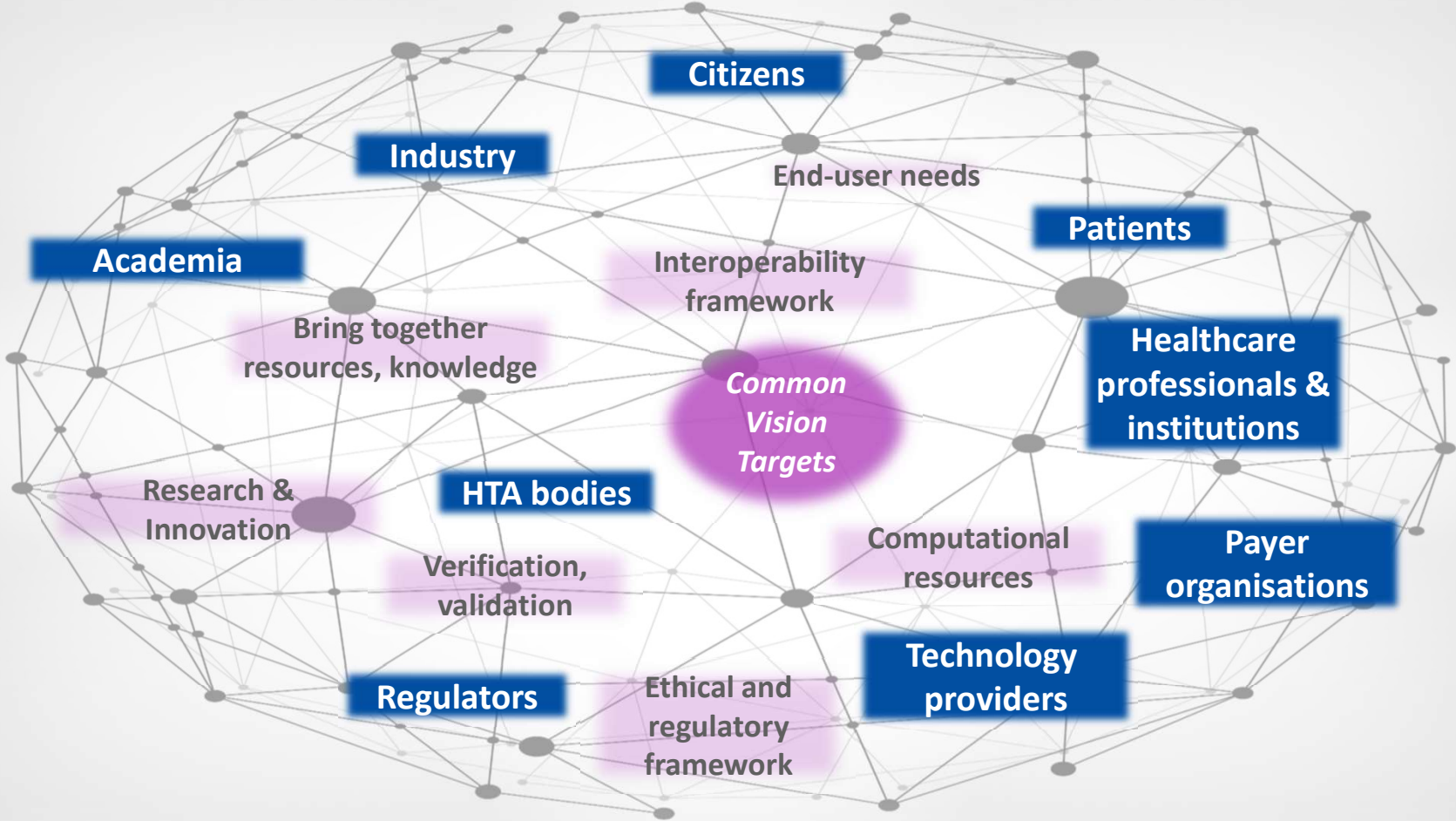
Citizens

Industry

End-user needs

Patients

Academia

Interoperability framework

Bring together resources, knowledge

Healthcare professionals & institutions

Common Vision Targets

Research & Innovation

HTA bodies

Computational resources

Payer organisations

Verification, validation

Regulators

Ethical and regulatory framework

Technology providers

European Commission

Thank you

Slide 9&10: pictures, source: pixabay.com

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