Exploring Efforts in Europe to Integrate Clinical Research with Clinical Care

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Novo Nordisk A/S

Meet the Speaker

Jesper Kjær

Title: Global Director for Public, Private Partnerships

Organization: Novo Nordisk

Global Head of Public, Private Partnerships at Novo Nordisk.

Co-lead for TransCelerate EHR connectivity workstream. Steering Board member of HL7 Vulcan.

National Advisory to the Danish Ministry of Health and Interior for One Entry Point to Danish Health Data.

Former co-chair for HMA / EMA Big Data Steering Group and Director of the Danish Medicines Agencies Data Analytics Centre (DAC).

25+ years experience in academia, industry and regulatory.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

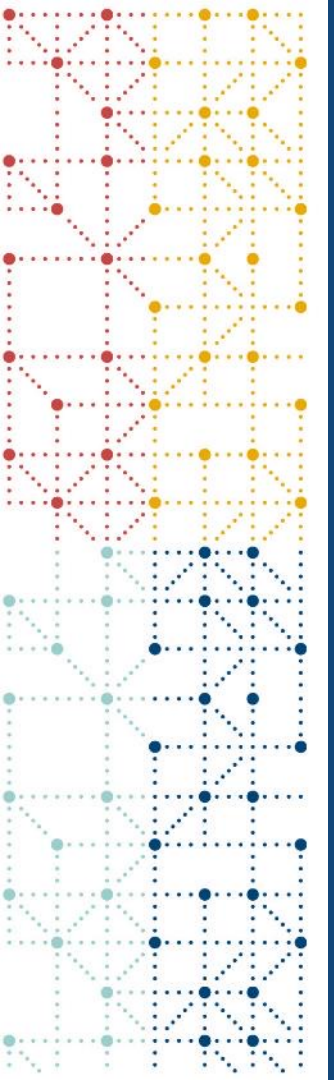
1. EU Framework programmes
2. Europe Digital Decade and European Health Data Space (EHDS)
3. Projects towards EHDS
4. IHI projects: a peek into the future
5. Conclusion

Exploring Efforts in Europe to Integrate Clinical Research with Clinical Care

- European Union / Commission has for several decades supported research in Europe through Framework Programmes (FP)

- Focus for many of the initiatives under these FPs has been to create cross border collaboration, elevate research and create innovation leading to new jobs

- Since 2012 under this also the worlds largest public, private partnerships frameworks: Innovative Medicines / Health Initiative (IMI, IMI2, IHI) has been funded



EU Framework programmes

European Commission

EN

Search

Public Health

Home > Funding > EU4Health programme 2021-2027 – a vision for a healthier European Union

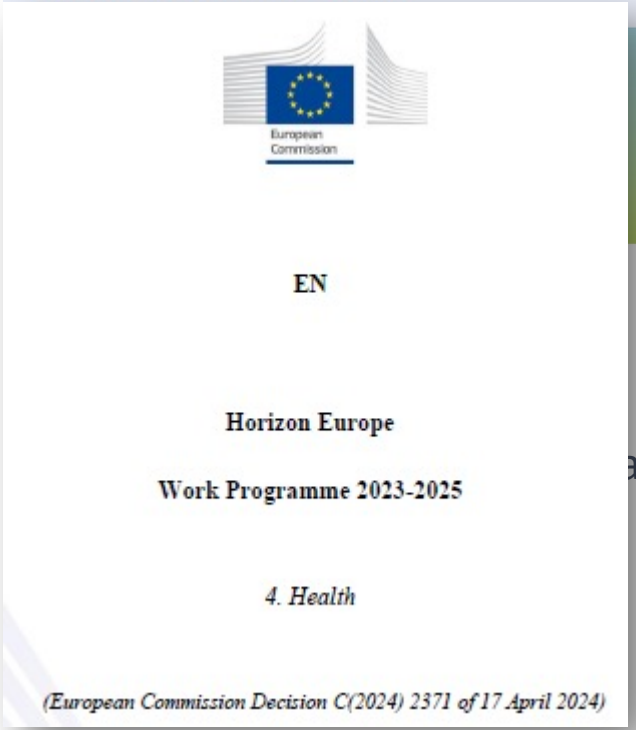
EU4Health programme 2021-2027 – a vision for a healthier European Union

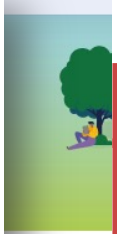
Two important instruments under EU4Health:

Horizon Europe
Innovative Health Initiatives

European Commission

Research and innovation





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cdisc

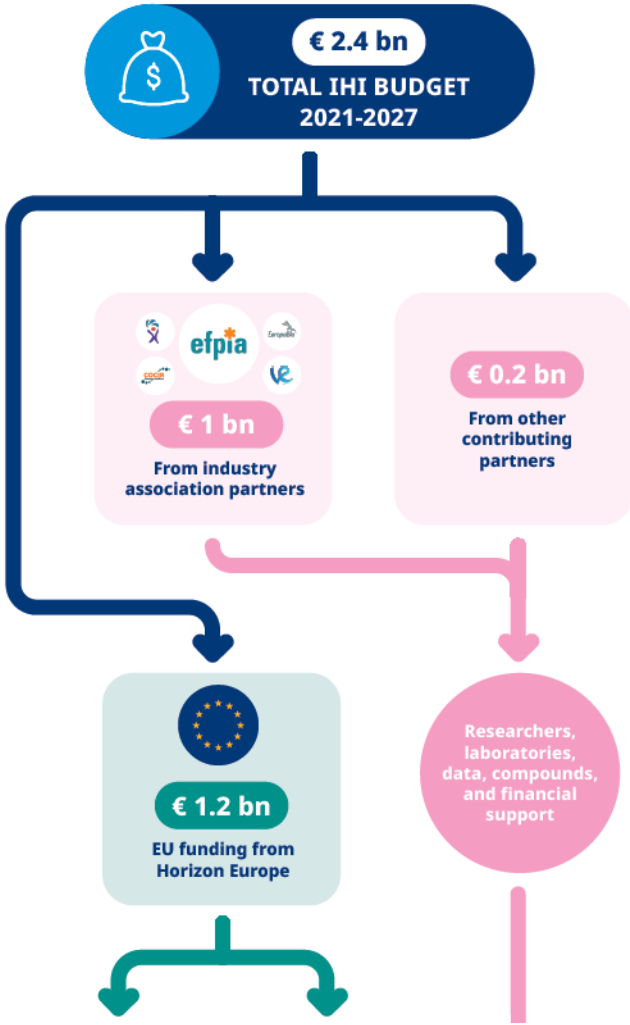
Innovative Health Initiative (IHI)

Transforming research to innovation

- Formerly the **Innovative Medicines Initiative (IMI)**
- World's largest Public-Private Partnership framework within health technology and life sciences

imi innovative medicines initiative

ihi innovative health initiative



Real World Data in IMI & IMI2

https://www.ihi.europa.eu/projects-results/project-factsheets/

https://www.ihi.europa.eu/projects-results/project-factsheets/ehr4cr

Facts & figures

Start Date	01/03/2011
End Date	29/02/2016
Call	IMI1 - Call 2
Grant agreement number	115189

Type of Action:
RIA (Research and Innovation Action)

Contributions	**€**
EU funding	7 194 044
EFPIA contribution	7 555 883
Other	1 893 502
Total Cost	16 643 429

Objective:

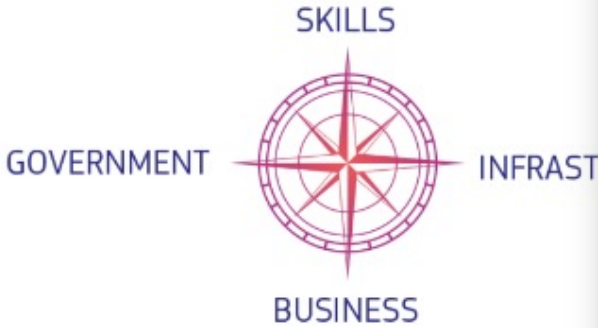
Develop a platform to reuse electronic health records for clinical research while ensuring data privacy and security.

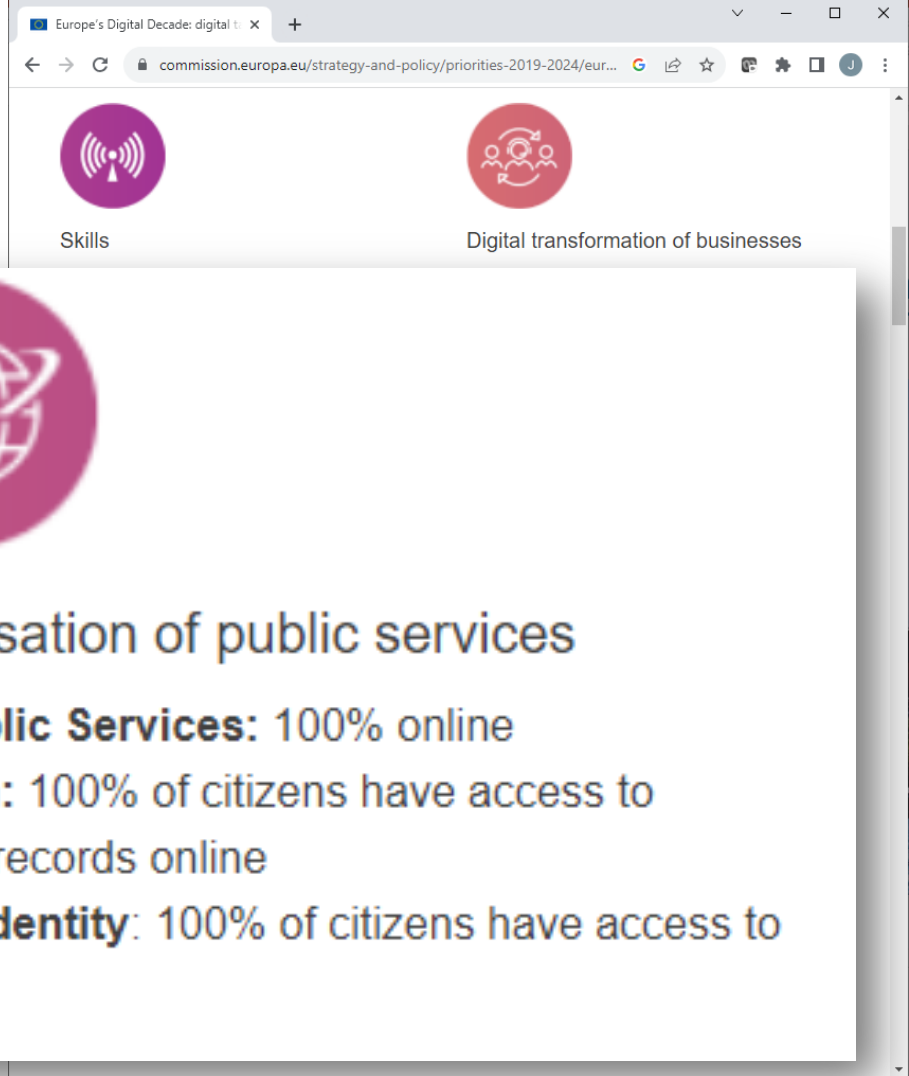
Focus:

Interoperability of EHRs, data integration, and use in clinical trials.

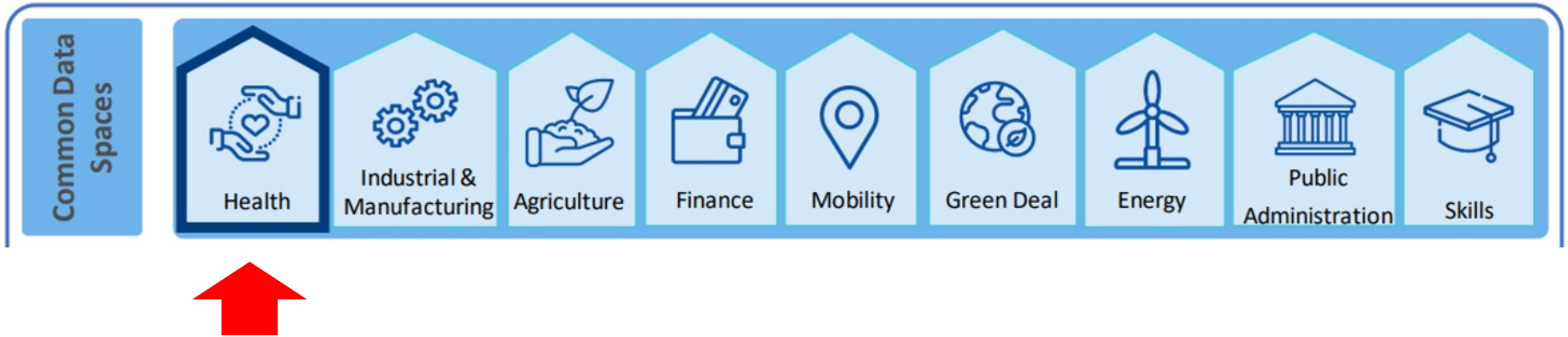
Europe Digital Decade and European Health Data Space (EHDS)

Europe's Digital Decade: digital targets for 2030





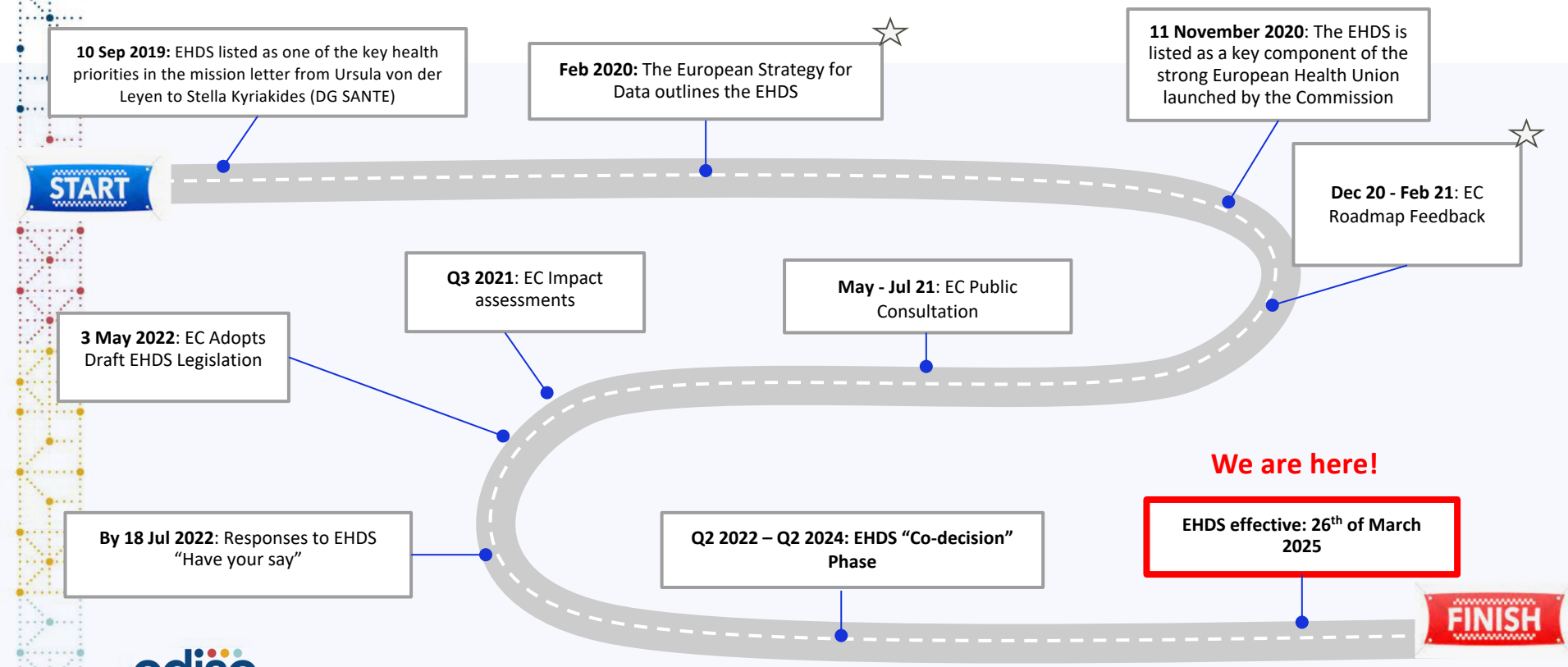
A common European Health Data Space (EHDS)



"The EHDS will be a crucial component of a strong European Health Union. It will enable EU-wide collaboration for better healthcare, better research and better health policy making. I invite all interested citizens and stakeholders to take part in the consultation and help us leverage the power of data for our health. This will have to rest on a strong foundation of non-negotiable citizens' rights, including privacy and data protection."
Stella Kyriakides, Commissioner for Health and Food Safety

From DIA Euro 2023: The European Health Data Space (EHDS): Can this Legislation unlock the Power of Health Data to Stimulate Innovation in Europe?, Tom Brookland, EU Data Policy Lead, Hoffmann La Roche, Switzerland

The EHDS History



From DIA Euro 2023: The European Health Data Space (EHDS): Can this Legislation unlock the Power of Health Data to Stimulate Innovation in Europe?, Tom Brookland, EU Data Policy Lead, Hoffmann La Roche, Switzerland

EUROPEAN COMMISSION

Strasbourg,
3.5.2022

COM(2022)
197 final

2022/0140(COD)

Proposal for a

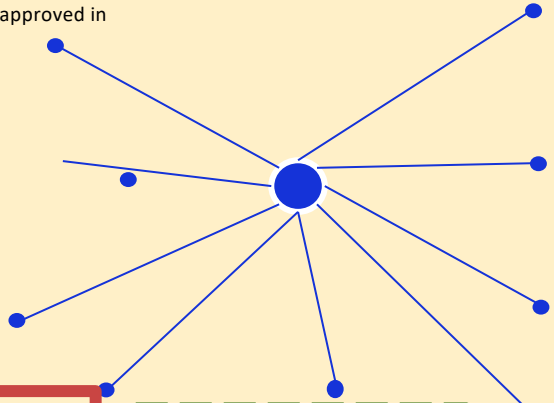
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

The EHDS: Another Policy in a Rapidly Evolving and Highly interconnected Data and Digital Policy Landscape

THE EUROPEAN DATA STRATEGY

SHAPING EUROPE'S DIGITAL FUTURE



General Data Protection Regulation (GDPR)

- Unifying data privacy laws across the EU and approved in 2016

Data Governance Act (DGA)

- Awaiting formal adoption by EP and Council
- Rules to apply 15 months after adoption

Data Act

- Draft legislation published on 23 Feb. 2022
- EP and Council debating proposal

European Health Data Space (EHDS)

- Part of the Pharma Strategy for the EU
- Draft adopted on 5 Apr. 2022

EMA/HMA Big Data Steering Group

DARWIN EU

Artificial Intelligence (AI) Act

- Proposal published in April 2021
- Discussions ongoing in EP and Council
- Rules to apply 15 months after adoption

Cybersecurity

- Review of (NIS2) Directive - in trilogue (negotiations between EP, Council and Commission)
- European Cyber Resilience Act (released Sept 2022)

Digital Service Act (DSA)

- Proposal published in Dec. 2020 and adopted in Jul. 2022
- Expected to be implemented in 2023

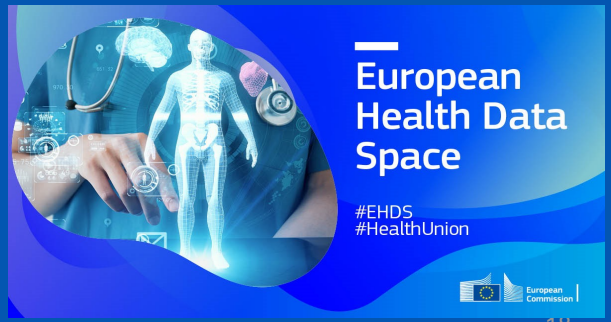
Digital Market Act (DMA)

- Proposal published in Dec. 2020 and adopted in Mar. 2022
- Expected to be implemented in 2023

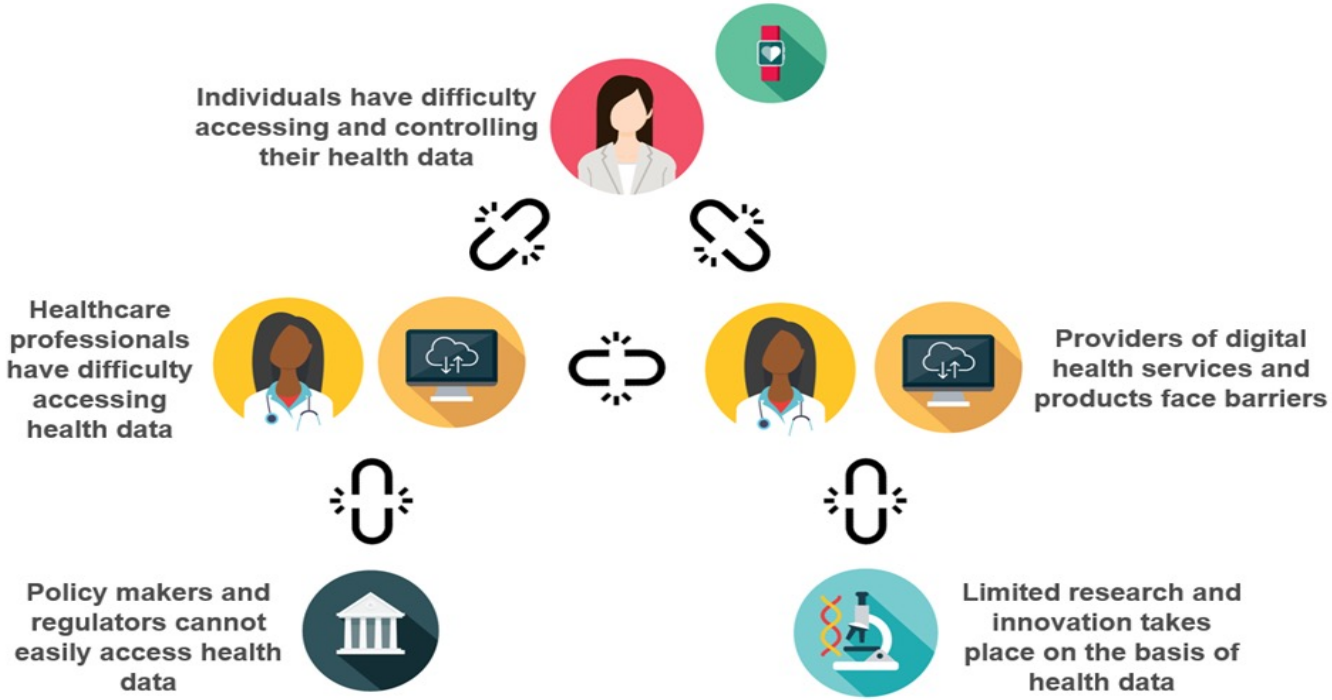
The EHDS is also connected to many other EU initiatives: EU Pharmaceutical Legislation, Europe's Beating Cancer Plan, EU MDR and IVDR, European Digital Identity initiative, DARWIN, TEHDAS…

European Health Data Space

Harnessing the power of health data for people, patients and innovation



Main challenges in harnessing the power of health data



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

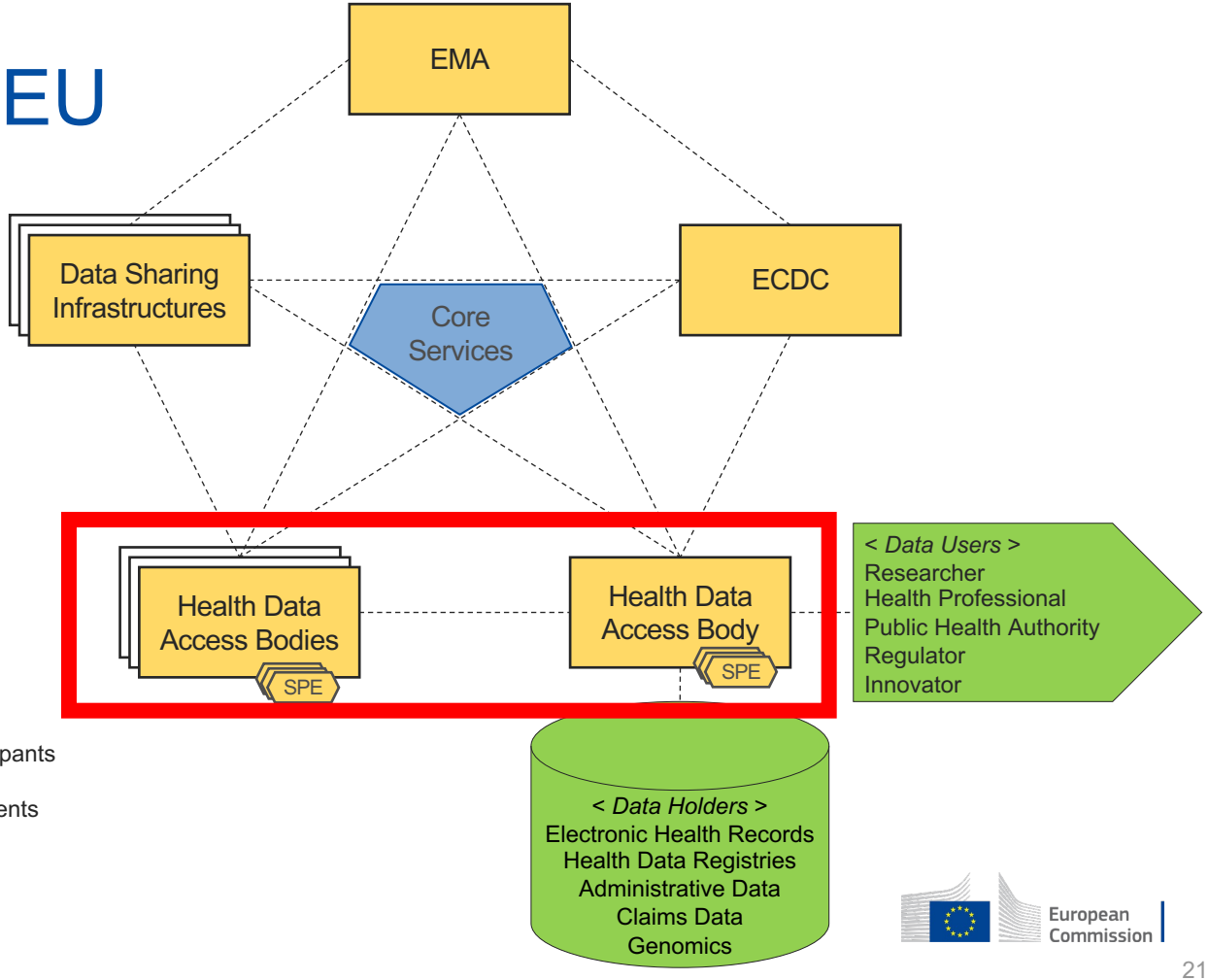
→ Facilitated Research & Innovation

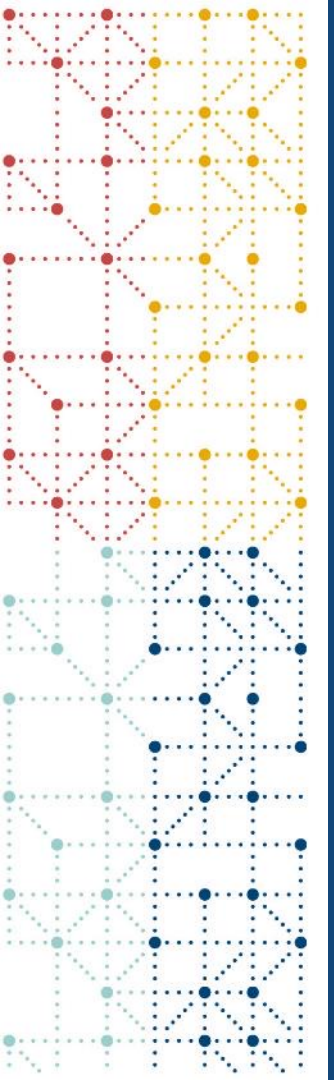
→ Better Policy Making

MEANS

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

HealthData@EU





Projects towards EHDS

EU projects to support and develop EHDS

EHDS
HealthData@EU Pilot

Quantum

TEHDAS2 Towards European Health Data Space

TEHDAS2 joint action advances the cross-border secondary use of health data in Europe to improve research, innovation and policymaking.

What is our goal?

Our goal is to develop common guidelines and technical specifications to facilitate smooth access to health data and strengthen European collaboration in using data efficiently. Secondary use of health data enhances competitiveness of European research and innovation in the health sector.

https://tehdas.eu/wp-content/uploads/2024/09/tehdas2-brief-leaflet-7.pdf

1. Draft guideline for Health Data Access Bodies on **fees and penalties for non-compliance** regulated to the EHDS regulation
2. Draft guideline for Health Data Access Bodies on **minimum categories and limitations on the reuse of health data**
3. Draft guideline for data holders on **making personal and non-personal electronic health data available** for reuse
4. Draft guideline for Health Data Access Bodies on the **procedures and formats for data access**
5. **Data Access Application Management System (DAAMS)** – Draft technical specification for health data access bodies
6. Draft technical specification for Health Data Access Bodies on **data minimisation and de-identification**
7. Draft technical specification for Health Data Access Bodies on the **implementation of the common IT infrastructure**
8. Draft technical specification for Health Data Access Bodies on the **implementation of secure processing environments**
9. Draft guideline for Health Data Access Bodies on implementing **opt-out from the secondary use of health data**
10. Draft guideline for Health Data Access Bodies on implementing the obligation of **notifying the natural person on a significant finding from the secondary use of health data**

HEALTH DATA HUB

Health Data Hub

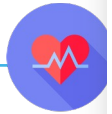
European Health Data Space Pilot

Use cases

Surveillance of antimicrobial resistance

Led by

ecdc
EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL



Comparing Nationwide He
to evaluate European
interoperabil
an application to cardiom

Led by

cdisc

EHDS

Deliverable 9.1

Use Cases report

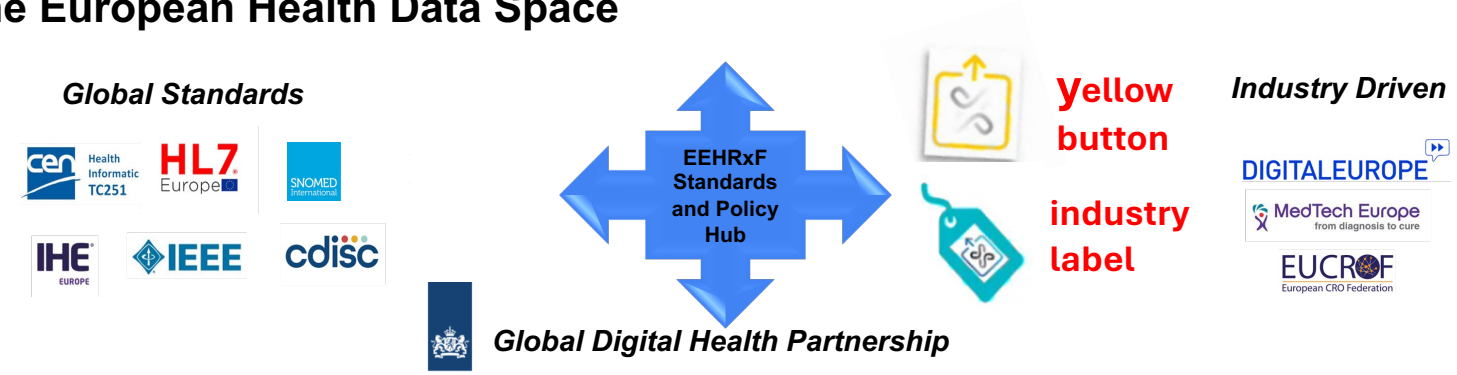
December 2024

xShare: Expanding the European EHRxF to share and effectively use health data within the EHDS

Co-funded by
the European Union

xShare vision:

Everyone can share their health data in EEHRxF with a click-of-a-button in the European Health Data Space



- Three are the main elements of implementing this vision:
  - The **Button** (the yellow button): illustrates this capability
  - The **HUB** (the EHRxF HUB): brings together global standards with industry and government to steward EHRxF specifications and accelerate adoption
  - The **Label** (the industry label): demonstrates the commitment and capability of the industry to implement EEHRxF

Co-funded by the European Union

The xShare Consortium

xShare
EHR Xchange Format

Coordination

medcom
HL7 Europe

European EHRxF standards Hub (6 SDOs)

CEN Health Informatics TC251
HL7 Europe
DIGITALEUROPE
IHE EUROPE
IEEE
SNOMED International
cdisc
DNV

Action line #1 Data portability

gnomon INFORMATICS
UNINOVA

Action line #3 Clinical Research

iHD
EUCROF European CRO Federation

Action line #2 Population Health

EHTEL
CHARITÉ

X-Share Xbubbles: Demonstration & Scale up (9-11 countries)

Generalitat de Catalunya Departament de Salut
HAIKA
medcom
TicSalut
University of Cyprus
National eHealth Authority
Região Autónoma da Madeira Governo Regional
sciensano Belgian institute for health
DANISH HEALTH DATA AUTHORITY

SMEs (6) and Trade Associations (3+)

gnomon INFORMATICS
DIGITALEUROPE
MedTech Europe from diagnosis to cure
telemedicine technologies
CINECA
Datawizard
MEDIQ
EUCROF European CRO Federation

Monitoring & Evaluation

empirica

Capacity Building, Security & Privacy, Innovative Procurement

iscte
FORTH INSTITUTE OF COMPUTER SCIENCE

Stakeholder Engagement/ Expert Roster

ECHAlliance

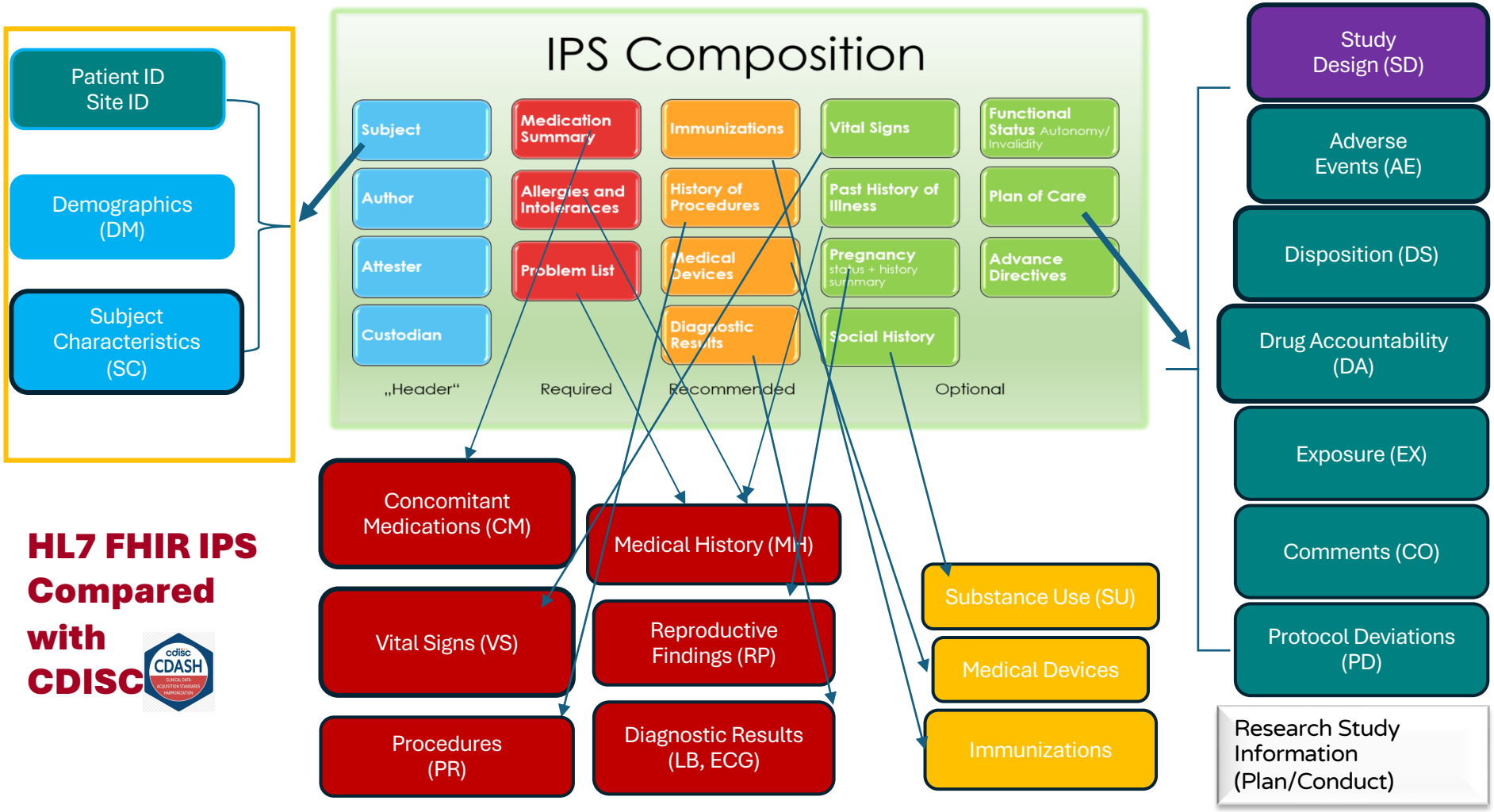
Research Infrastructures & Registries

CINECA

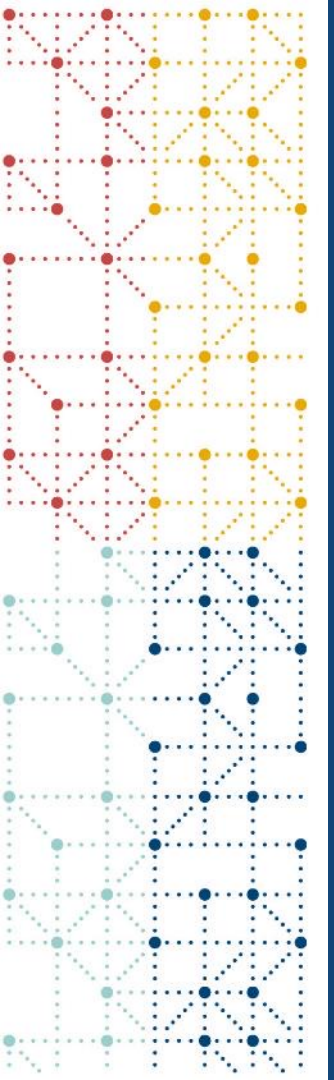
Associated Partners

DANISH HEALTH DATA AUTHORITY
MedTech Europe from diagnosis to cure
Ministry of Health, Welfare and Sport
SANOFI

Co-funded by the European Union



HL7 FHIR IPS Compared with CDISC



IHI projects: a peek into the future

IHI projects: a peek into the future

Topic 3: AI-Powered Signal Detection in Pharmacovigilance

Safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

HORIZON-JU-IHI-2025-10-02-two-stage

RWE Guidance from regulatory and HTA bodies

FDA, USA

2017 - Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

2018 - Use of Electronic Health Record Data in Clinical Investigations

2021, draft - Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products

2021, draft - Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products

2021, draft - Data Standards for Drug and Biological Product Submissions Containing Real-World Data

2022 - Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products

2023, draft - Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products

2023 - Considerations for the Use of RWD and RWE To Support Regulatory Decision-Making for Drug and Biological Products

2024, draft – RWE: Considerations regarding NIS for Drug and Biological Products

EMA, EU

2021 – Guideline on registry-based studies

2023 – Data Quality Framework for EU medicines regulation

ICH, M14

General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize RWD for safety assessment of medicines

ENCePP, EU

2023 – Guide on Methodological Standards in Pharmacoepidemiology, Rev. 11

Swissmedic, CH

2023 - Swissmedic position paper on the use of real world evidence

HAS, FR

2021 - Real-world studies for the assessment of medicinal products and medical devices

MHRA, UK

2021 – Guidance on the use of RWD in clinical studies to support regulatory decisions

2021 – Guideline on randomized controlled trials using RWD to support regulatory decisions

NICE*, UK

2022 – NICE RWE Framework

Health Canada

2018 - Use of Electronic Health Record Data in Clinical Investigations

Canada's D&HTA* (+ Health Canada)

2023 – Guidance for reporting RWE

PMDA, Japan

2014 – Guidelines for the conduct of pharmacoepidemiological studies in drug safety assessment with medical information databases

2017 – Basic Principles on the use of medical information databases in post-marketing pharmacovigilance

2020 – Points to consider for ensuring the reliability of post-marketing database study for regenerative medical products

2021 – Basic Principles on utilization of registry for applications

NMPA, China

2021 – Guidance for Real-World Data Used to Generate Real-World Evidences (Interim)

2022 – Guidance on the Use of Real-World Evidence to Support Drug Development and Regulatory Decisions

2023 – Guidance on Communication with Regulatory Agency on Real- World Studies to Support Product Registration

2023 – Guidance on the Design and Protocol Development of Real-World Studies for Drugs

* Health Technology Assessment Agency

Source: Joint HMA/EMA Big Data Steering Group workshop on real-world evidence (RWE) methods – 2024-JUN-14

Conclusions

Europe has 2030 focus on a digital decade and under this to enable EHDS

The solutions to EHDS are being established through both national investments but moreover through common approaches agreed via the different projects under EU4Health

It is estimated that savings in health care can reach 11 billion Euros over a decade across the EU through better use of data

Horizon Europe and IHI have a range of initiatives that will drive the development of EHDS and a better integration of clinical research with clinical care through the primary and secondary use of data

Thank You!