Demystifying the EU Data Sharing Space

Welcome

Keynote

The European Health Data Space (EHDS)

Panel: IPD Data Sharing in the EU

Luca Pani
Professor of Pharmacology, **University of Modena and Reggia Emilia,** Professor of Clinical Psychology, **University of Miami**

Virginia Nido
Global Head, Product Development Industry Collaborations, **Roche,** Co-Founder, **CRDSA**

CRDSA
Clinical Research Data Sharing Alliance

2025 CRDSA Summit

Patient Data Reuse: Latest Developments and Expert Insights

Demystifying the EU Data Sharing Space Day 2

The second day of the summit is all about the European data space. What will be the impact of the European Health Data Space? What's on the horizon for IHI/IMI projects like FACILITATE and IDEHRA? How will EMA's DARWIN EU be used to inform regulatory decision-making? Sessions will address how these initiatives work together (and where they don't), with a focus on the role of industry, both as data providers and data users.

Keynote: Luca Pani
Professor of Pharmacology, **University of Modena and Reggia Emilia,** Professor of Clinical Psychology, **University of Miami**

Host: Virginia Nido
Global Head, Product Development Industry Collaborations, **Roche,** Co-Founder, **CRDSA,**

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Executive Director, **Good Clinical Practice Alliance – Europe (GCPA),** Chair, **CODATA International Data Policy Committee (IDPC)**

Peter Mesenbrink
Executive Director of Biostatistics, **Novartis,** Board Chair, **CRDSA**

Cecile Ollivier
Vice President of Global Affairs, **Critical Path Institute**

Moderator: Aaron Mann
CEO, **CRDSA**

January 29, 2025

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Last update: Jan 25th , 2025

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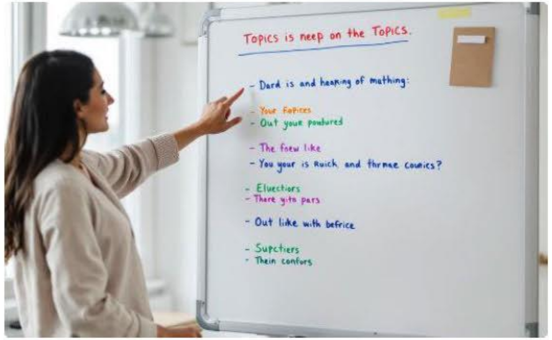
Demystifying the EU Data Sharing Space

Content Overview



Healthcare Data Sharing in the EU

Understanding the evolving landscape and its global and local implications.

Key Institutions & Roles

Exploring the roles of key players in shaping the data sharing ecosystem.

Opportunities & Challenges

Examining the potential benefits and hurdles of data sharing in the EU. The case example of the FACILITATE IMI-2 Project.

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https://facilitate-project.eu/

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EU Key Institutions on the present topic

- ✓ **European Commission**
  - Proposes and implements legislation like the Data Governance Act and Data Act; coordinates EHDS.
- ✓ **EMA**
  - Central authority for drug approval and pharmacovigilance in the EU.
- ✓ **IHI**
  - Successor to the Innovative Medicines Initiative (IMI), focusing on cross-sector health innovation.

The Benefits of Data Sharing in the EU are clear.

Larger Datasets

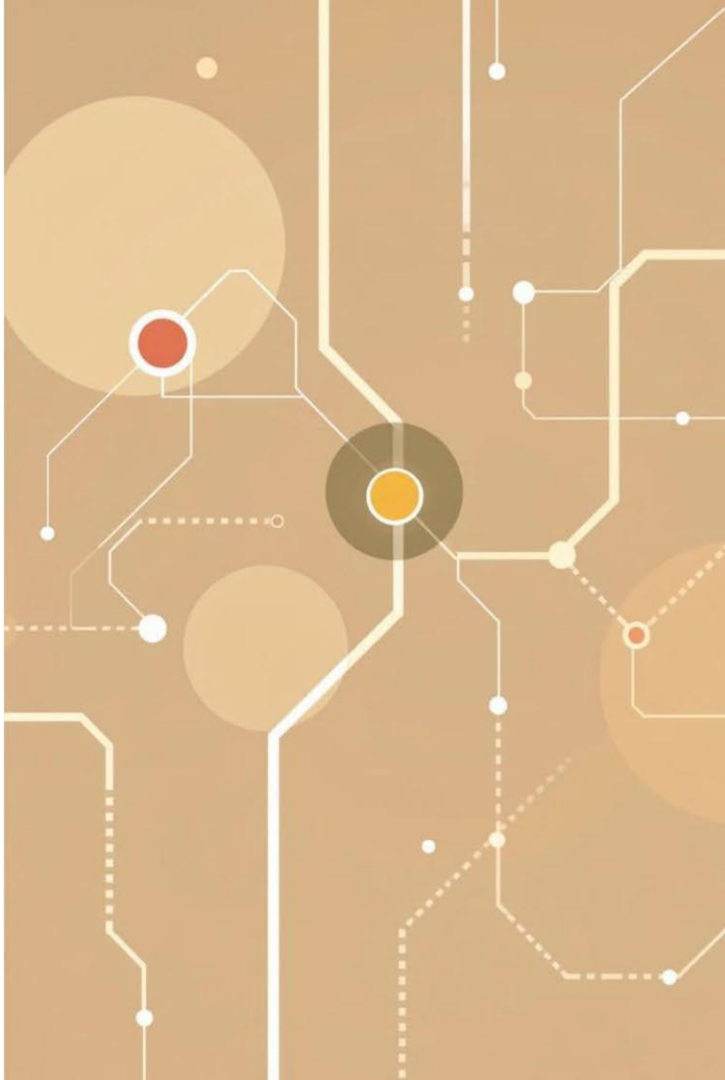
Combining data across EU member states yields more robust, representative information for clinical research.

Real-World Evidence

Shared data can drive faster drug approvals and post- marketing surveillance.

AI & Innovation

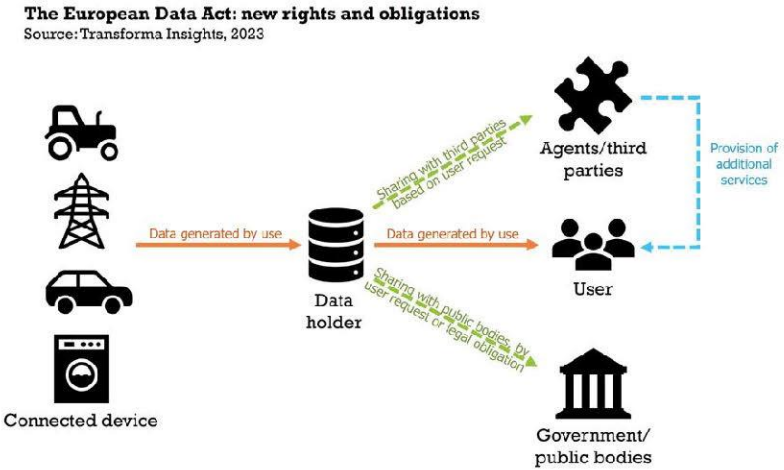
Better data access fuels advanced analytics, including machine learning algorithms that improve diagnostics and treatment plans.



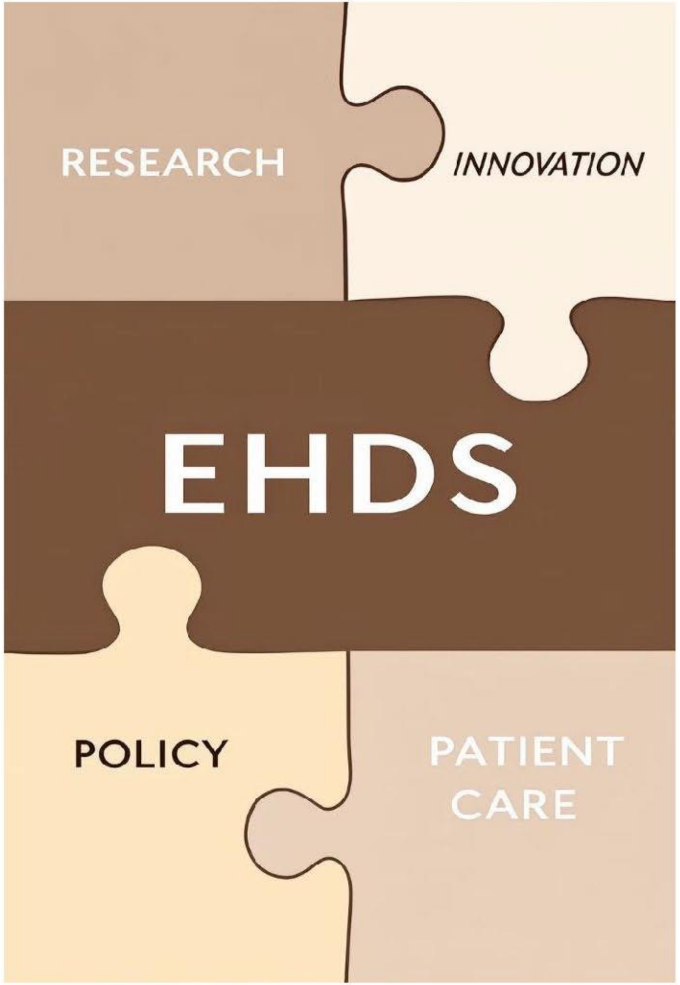
EU Data Sharing Landscape

The EU has established a comprehensive data sharing landscape, built on foundational legislation and initiatives.

- General Data Protection Regulation (GDPR): Protects personal data.
- Data Governance Act (DGA): Fosters trusted data intermediaries.
- Proposed Data Act (PDA): Clarifies data usage rights.
- European Health Data Space (EHDS): Dedicated to health data sharing



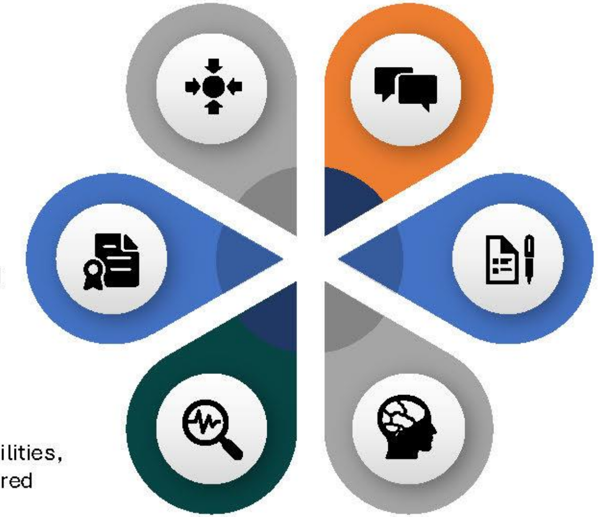
The European Data Act: new rights and obligations
Source: Transforma Insights, 2023



Intentions of the European Health Data Space (EHDS)

- Facilitates research and innovation.
- Prioritizes privacy and security.
- Enhances data interoperability across systems.

However, there are many infrastructural hurdles to ensuring that the EHDS Intentions could be executed



01 SILOED DATA THAT REQUIRES HARMONIZATION

RWD currently exist in different siloes, including EHRs, patient and physician registries, claims databases etc. Integrating and harmonizing these disparate sources offers opportunities to expand RWD analyses[1]

02 UNCERTAIN DATA QUALITY AND PROVENANCE

EHR is not organized with the goal of supporting research and the accuracy / reliability of data gathered by many personal devices and health-related apps are uncertain[2]

03 POOR DATA INTEGRITY & SECURITY & NEED FOR DE-IDENTIFICATION

Attacks on RWD are prevalent due to security vulnerabilities, particularly in emerging economies, challenging a desired level of data integrity[3]

NEED FOR DE-CENTRALIZED & HYBRID STUDIES 04

Studies that are completed at the point of care and incorporate RWE allow patients to receive treatments from their community providers while ensuring data collected is accurate and reliable[5]

DIFFICULTIES IN EXTRACTING DATA FROM UNSTRUCTURED SOURCES 05

Extraction can be difficult in retrospective data collection, which is often based on unstructured texts like discharge letters or medical records[4]

GAPS IN TECHNICAL EXPERTISE 06

Shortage of researchers with adequate methodologic savvy could result in poorly conceived study and analytic designs that generate incorrect or unreliable conclusions[2]

Abbreviations: RWD: Real world data; RWE: Real world evidence; EHR: Electronic health record.

1. National Institute on Aging (NIA). 2022. Gaps and opportunities for real-world data infrastructure. 2. Sherman et al. 2016. Real-world evidence — what is it and what can it tell us? 3. Pertacci et al. 2021. Use of real-world evidence for oncology clinical decision making in emerging economies. 4. Loda et al. 2019. Exploration of artificial intelligence use with ARIES in multiple myeloma research. 5. Gottlieb. 2019. Breaking down barriers between clinical trials and clinical care: incorporating real world evidence into regulatory decision making.

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The higher the quality of RWE, the higher the requirements for data collection infrastructure

EHR[1,2]

- Electronic system to collect and store patients' medical information[1]
- Enables quick access to patient records and more reliable prescription[2]
- Limited interoperability with other health information systems[1]

Patient registry[4]

- Organized systems that collect uniform data on a population defined by a particular disease, condition or exposure[4]
- Plays an important role in monitoring the safety of medicines[4]
- Challenges in data sharing and transparency[4]

Registry networks[5,7]

- Linkage of registries and a diverse range of other datasets[5]
- Facilitate knowledge sharing, standards for improved interoperability and registry practice professional communities[7]
- Challenges in data harmonization / sharing due to divergent national rules[7]

Registry-based randomized trial[3,6]

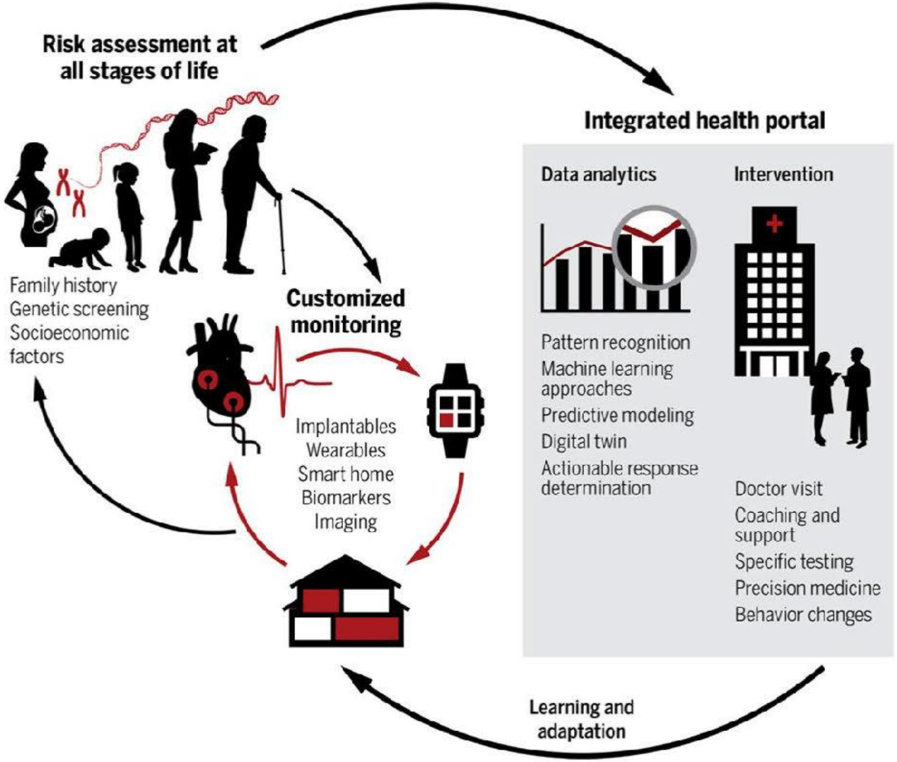
- Trials that use registries as a platform for case records, data collection, randomization, and follow-up[3]
- Requires well-established national registries, with standardized end points and little missing data[6]

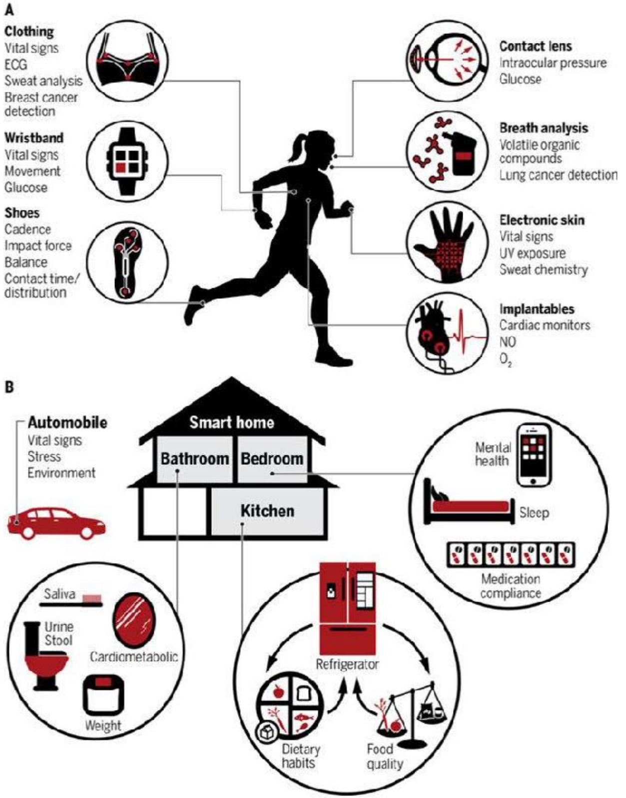
Infrastructure requirement

Abbreviations: EHR: Electronic health record; RWE: Real world evidence; RCT: Randomized controlled trial.

1. Ehrenstein et al. 2019. Obtaining data from electronic health records. 2. HealthIT.gov. 2023. What are the advantages of electronic health records. 3. Li et al. 2016. Registry-based randomized controlled trials - what are the advantages, challenges, and areas for future research. 4. EMA. 2023. Patient registries. 5. Sedrakyan et al. 2022. Advancing the real-world evidence for medical devices through coordinated registry networks. 6. Doherty et al. 2023. Registry randomised trials: a methodological perspective. 7. L&M Policy Research, LLC. 2018. Registries for Evaluating Patient Outcomes: A User's Guide.

Remember that People are a Continuous Source of Health Data





ECG = electrocardiogram; NO = nitric oxide; O2 = oxygen; UV = ultraviolet.
Gambhir SS, et Al. Toward achieving precision health. Sci Transl Med. 2018 Feb 28;10(430)

On RWE, the EU and US laws and, therefore, actions diverge

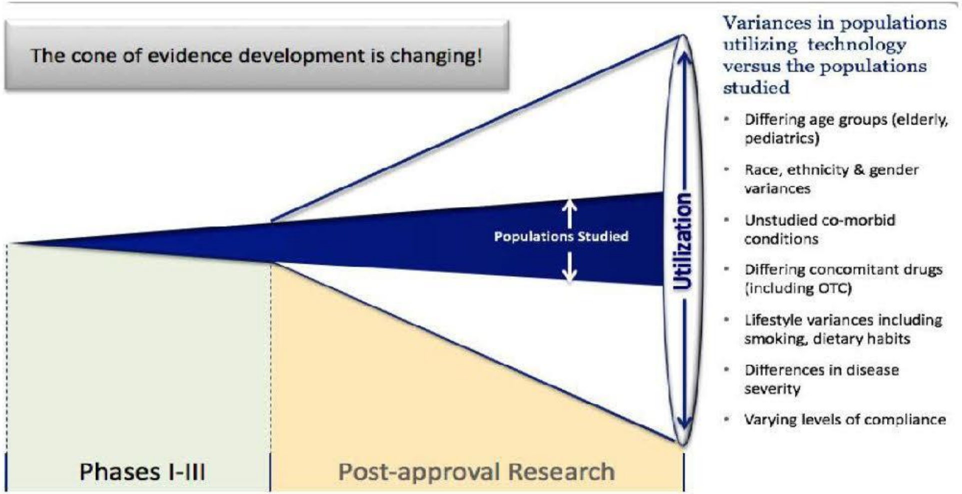
≠

In EU one early workshop (about 2018)

Real world evidence – what have we learned recently at EMA?

An agency of the European Union

Kieran Breen, Jamie Wilkinson, Courtney Coleman, Isabel Proano, Sofia Marcha, Birgit Bauer
RWE sub-group



Variances in populations utilizing technology versus the populations studied

- Differing age groups (elderly, pediatrics)
- Race, ethnicity & gender variances
- Unstudied co-morbid conditions
- Differing concomitant drugs (including OTC)
- Lifestyle variances including smoking, dietary habits
- Differences in disease severity
- Varying levels of compliance

- What impacts access to data?
  - GDPR regulations
  - National and local guidelines
  - Role of anonymity
  - Storage and security

In EU: 1 Strategy, 1 early Guideline (oct 2021), 1 Paper

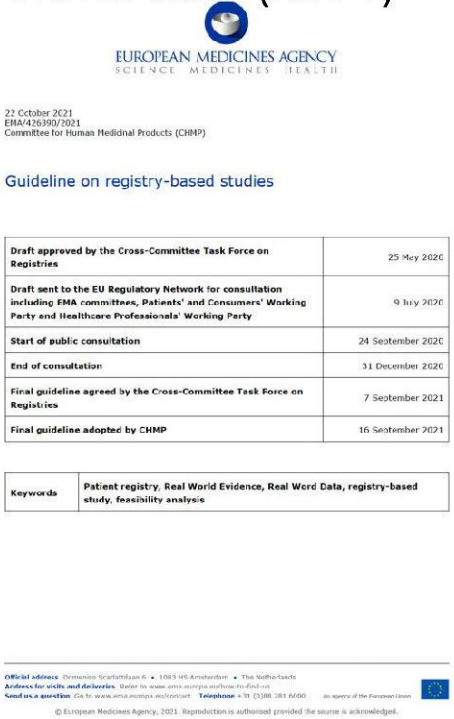
Real-World evidence (RWE) is the evidence derived from the analysis and/or synthesis of Real-World data (RWD)

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European medicines agencies network strategy to 2025

Protecting public health at a time of rapid change



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 October 2021
EMA/426390/2021
Committee for Human Medicinal Products (CHMP)

Guideline on registry-based studies

Draft approved by the Cross-Committee Task Force on Registries	25 May 2020
Draft sent to the EU Regulatory Network for consultation including EMA committees, Patients' and Consumers' Working Party and Healthcare Professionals' Working Party	9 July 2020
Start of public consultation	24 September 2020
End of consultation	31 December 2020
Final guideline agreed by the Cross-Committee Task Force on Registries	7 September 2021
Final guideline adopted by CHMP	16 September 2021

Keywords	**Patient registry, Real World Evidence, Real Word Data, registry-based study, feasibility analysis**

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Check for updates

PERSPECTIVES

PERSPECTIVE

Real-World Evidence in EU Medicines Regulation: Enabling Use and Establishing Value

Peter Arlett[1],*, Jesper Kjær[2], Karl Broich[3] and Emer Cooke[1]

We outline our vision that by 2025 the use of real-world evidence will have been enabled and the value will have been established across the spectrum of regulatory use cases. We are working to deliver this vision through collaboration where we leverage the best that different stakeholders can bring. This vision will support the development and use of better medicines for patients.

Real-world data (RWD) and real-world evidence (RWE) are already used in the regulation of the development, authorization, and supervision of medicines in the European Union. Their place in safety monitoring and disease epidemiology are well-established while their evidentiary value for additional use cases, notably for demonstrating efficacy, requires further evaluation.[1] During the coronavirus disease 2019 (COVID-19) pandemic, RWE rapidly provided impactful evidence on drug safety, vaccine safety, and effectiveness and we were reminded of the importance of robust study methods and transparency.[2] Our vision, anchored in the European Medicines Regulatory Network (EMRN) strategy to 2025, is that by 2025 the use of RWE will have been enabled and the value will have been established across the spectrum of regulatory use cases.[3] Delivering this vision will support the development and use of better medicines for patients.

In December 2018, the US Food and Drug Administration (FDA) published its framework for RWE underpinned by three pillars: whether RWD are fit for use, whether the study design can provide adequate evidence, and whether the study conduct meets regulatory requirements.[4] In 2019 in the European Union, we published the OPTIMAL framework for RWE also consisting of three pillars: operational, technical, and methodological.[5] More recently the EU approach places RWE in the wider context of big data and is guided by the priority recommendations of the Big Data Task Force. These recommendations are being implemented through the Big Data Steering Group and the second multiannual work plan was published in August 2021.[6] **Figure 1** represents the workplan with its 11 workstreams which will deliver our vision for RWE by 2025. The workplan places emphasis on collaboration across stakeholders and with international regulatory partners. This work also needs to be seen in the wider EU policy context, most notably the European Commission's plans for a European Health Data Space.[7]

Acknowledging different frameworks to conceptualize the challenges and opportunities of RWE, we believe the two main priorities for the European Union are to enable its use and establish its value for regulatory decision making. The EMRN is working to deliver on both priorities through a collaborative approach where we leverage the best that different stakeholders can bring, and where those stakeholders can complement the central role of industry in generating evidence.

ENABLING USE

To enable use, we are working on multiple fronts with our stakeholders, including patients, healthcare professionals, industry, regulatory and public health agencies, health technology assessment bodies, payers, and academia. We are initiating work to establish a data quality framework, not just for RWD but for all data used in regulatory decision making. We are striving to improve the discoverability (findability) of RWD through agreement of metadata for RWD and through a public catalogue of RWD sources[8] that builds on the early work of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The ENCePP Guide on Methodological Standards in Pharmacoepidemiology,[9] extensively updated in 2021, is the core of our efforts to drive up the standards of study methods for RWE, and this is complemented by recently published guidance on conducting studies based on patient registries.[10]

The European Medicines Agency (EMA) and some national medicines agencies

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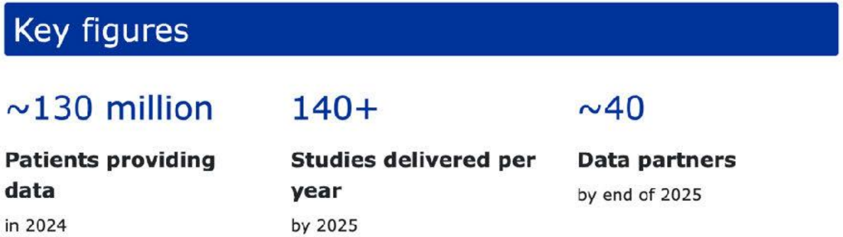
[1]European Medicines Agency, Amsterdam, Netherlands; [2]Danish Medicines Agency, Copenhagen, Denmark; [3]BfArM, Bonn, Germany. *Correspondence: Peter Arlett (Peter.Arlett@ema.europa.eu)

Received March 1, 2021; accepted November 1, 2021. doi:10.1002/cpt.2479

Most recently a larger and more coordinated effort

The European Medicines Agency (EMA) and the European Medicines Regulatory Network established a coordination centre to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union (EU). This capability is called the Data Analysis and Real World Interrogation Network (DARWIN EU®).



Key figures

~130 million	140+	~40
Patients providing data in 2024	**Studies delivered per year** by 2025	**Data partners** by end of 2025

Darwin EU supports regulatory decision-making by:

- establishing and expanding a catalogue of observational data sources for use in medicines regulation;
- providing a source of high-quality, validated real world data on the uses, safety and efficacy of medicines;
- addressing specific questions by carrying out high-quality, non-interventional studies, including developing scientific protocols, interrogating relevant data sources and interpreting and reporting study results.

https://www.ema.europa.eu/en/about-us/how-we-work/big-data/real-world-evidence/data-analysis-real-world-interrogation-network-darwin-eu

Establishment of EU full RWE and registries implementation for data sharing (and re-use?)

What may impact access to data in EU

- **GDPR – GDPR – GDPR!!! (but is true???)**
  - Challenges of development of RWE data including provision of informed consent
  - Clear communication with appropriate stakeholder involvement at all stages
- Inclusions of outcomes relevant to patients
  - Collection and analysis of meaningful data
  - Impact on willingness to take part
- Data acquisition
  - Motivation/reward (patient and clinician)
  - Accuracy, quality and point of entry
  - Collected in a "real world" setting (e.g. community or primary care)
- Data protection and custodianship

In US: 10 Guidance Documents (Aug. 2017; Sep. 2021: Oct. 2021; Dec. 2021; Sep. 2022, Aug. 2023, Dec. 2023, Dec. 2023; Jul. 2024, Sep. 2024); 1 Paper

Contains Nonbinding Recommendations

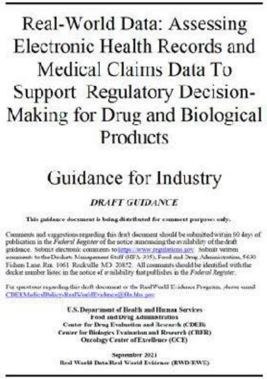
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Surveillance and Biometrics (OSB) at 301-796-5997 or CDRHClinicalEvidence@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.



Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document or the Real-World Evidence Program, please email CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

September 2021
Real World Data/Real World Evidence (RWD/RWE)

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

Guidance for Industry

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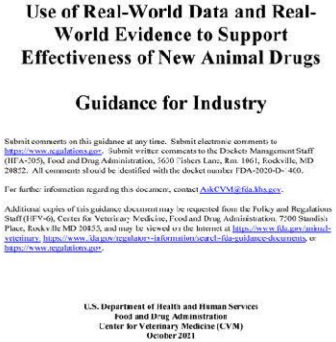
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2021
Real-World Data/Real-World Evidence (RWD/RWE)



Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs

Guidance for Industry

Submit comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2020-D-1400.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

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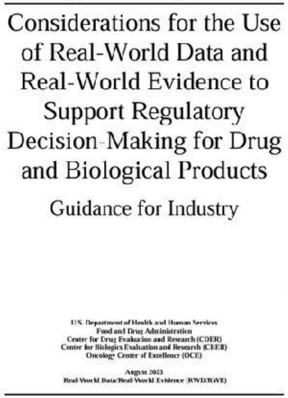
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
October 2021



Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

U.S. Department of Health and Human Services
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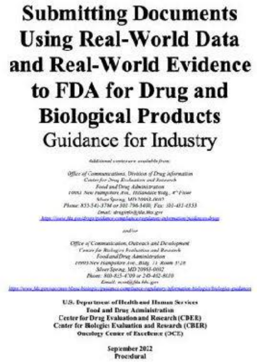
August 2023
Real-World Data/Real-World Evidence (RWD/RWE)



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

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov

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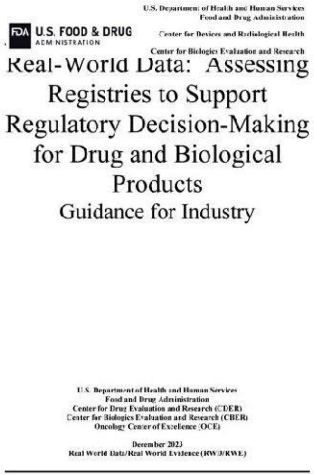
September 2022
Procedural



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U.S. FOOD & DRUG ADMINISTRATION

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December 2023
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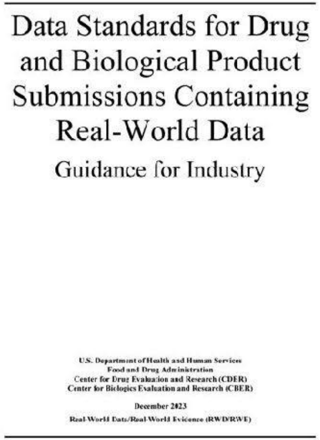

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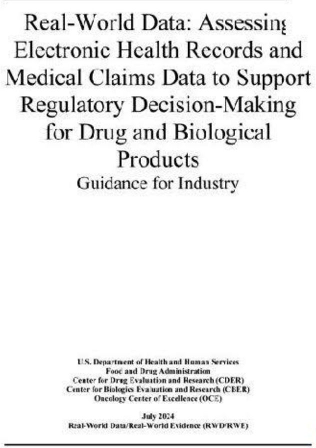

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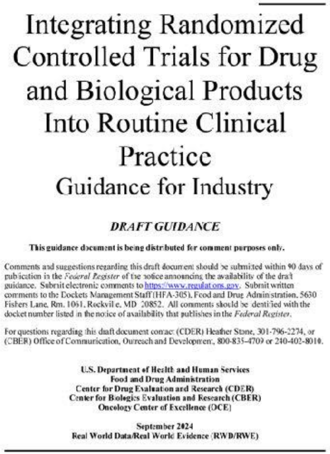
Oncology Center of Excellence (OCE)

July 2024
Real-World Data/Real-World Evidence (RWD/RWE)



Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Heather Stone, 301-796-2274, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

September 2024
Real World Data/Real World Evidence (RWD/RWE)

PERSPECTIVE

REAL-WORLD EVIDENCE — WHERE ARE WE NOW?

Real-World Evidence — Where Are We Now?

John Concato, M.D., M.P.H., and Jacqueline Corrigan-Curay, J.D., M.D.

More than 5 years after the passage of the 21st Century Cures Act of 2016, the terms "real-world data" (RWD) and "real-world evidence" (RWE) are being used inconsistently and sometimes interchangeably. This imprecision has complicated efforts to assess the impact of such data and evidence and hindered attempts to track their use.

The Food and Drug Administration (FDA), in its *Framework for FDA's Real-World Evidence Program*,[1] defined RWD as "data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources" and defined RWE as "clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD," regardless of the type of study design.

But there are two widespread misconceptions about these terms. The first is the notion that RWD and RWE were brand-new concepts in 2016. In reality, sources of data and types of study designs haven't fundamentally changed, but electronic access to more detailed clinical data is evolving, and such information's reliability and relevance to research are improving. The availability of more robust data on clinical factors that affect health outcomes also provides opportunities for exploring various statistical methods in lieu of randomization. Including "RWD" or "RWE" in the description of a study, however, doesn't tell us exactly where the data came from or what kind of study architecture is involved. Providing more specifics about data sources and study design can reduce confusion over RWD and RWE.[2]

The second misconception is that a simple dichotomy between randomized, controlled trials (RCTs) and observational studies delineates the entire landscape of study design.[3] Although randomization of treatment assignment is a key strength of RCTs, not all clinical trials are randomized; rather, their defining feature is assignment of treatment according to an investigational protocol. For example, in single-group trials, investigators assign participants to receive an intervention without randomization — and face challenges similar to those in observational studies in determining whether differences in clinical outcomes between the protocol-driven group and a comparator ("control") group represent actual treatment effects.

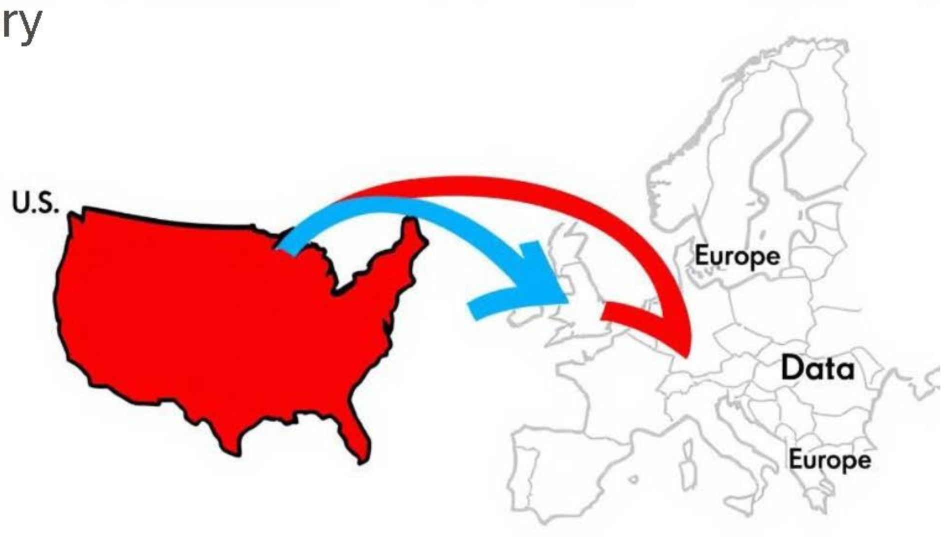
Correcting these misconceptions requires recognition that the degree of reliance on RWD varies with the type of study design and that, by definition, RCTs that incorporate RWD generate RWE (see diagram). This conceptualization confirms that even when strict eligibility criteria may limit the generalizability of trial results, trial participants exist, and their outcomes occur, in the "real world" — despite perceptions that generation of RWE occurs only outside clinical trials. Also, although the terms "clinical trials" and "observational studies" have clear meanings when used properly, the terms "interventional studies" and "noninterventional studies" have advantages in describing whether the treatment of interest was administered according to a study protocol.

These conceptual distinctions were less pertinent when causal inferences regarding therapeutic effectiveness relied mainly on interventional studies with primary data collected in traditional RCTs. Increasingly, however, RCTs incorporate RWD, and when randomization isn't feasible for ethical or other reasons, externally controlled trials include a comparator group derived entirely from a source of secondary data ("external" to the treatment group). Conversely, noninterventional studies that analyze primary data collected from registries are being conducted more often.

Notwithstanding confusion regarding these terms and concepts, we at the FDA continue to evaluate RWD and RWE as we consider regulatory decisions. Indeed, the agency published four related draft guidance documents in 2021.[4] FDA guidance on data from electronic health records and medical claims databases includes recommendations on how to select relevant data sources and define and validate study variables; other guidance provides recommendations on designing or using an existing registry to support regulatory decision making. A guidance document on data standards advises sponsors to document a rationale for changes

Global Context & FDA Connections

- ✓ Comparisons with the U.S. regulatory environment (FDA).
- ✓ Cross-border research challenges.
- ✓ Potential harmonization or conflict areas.

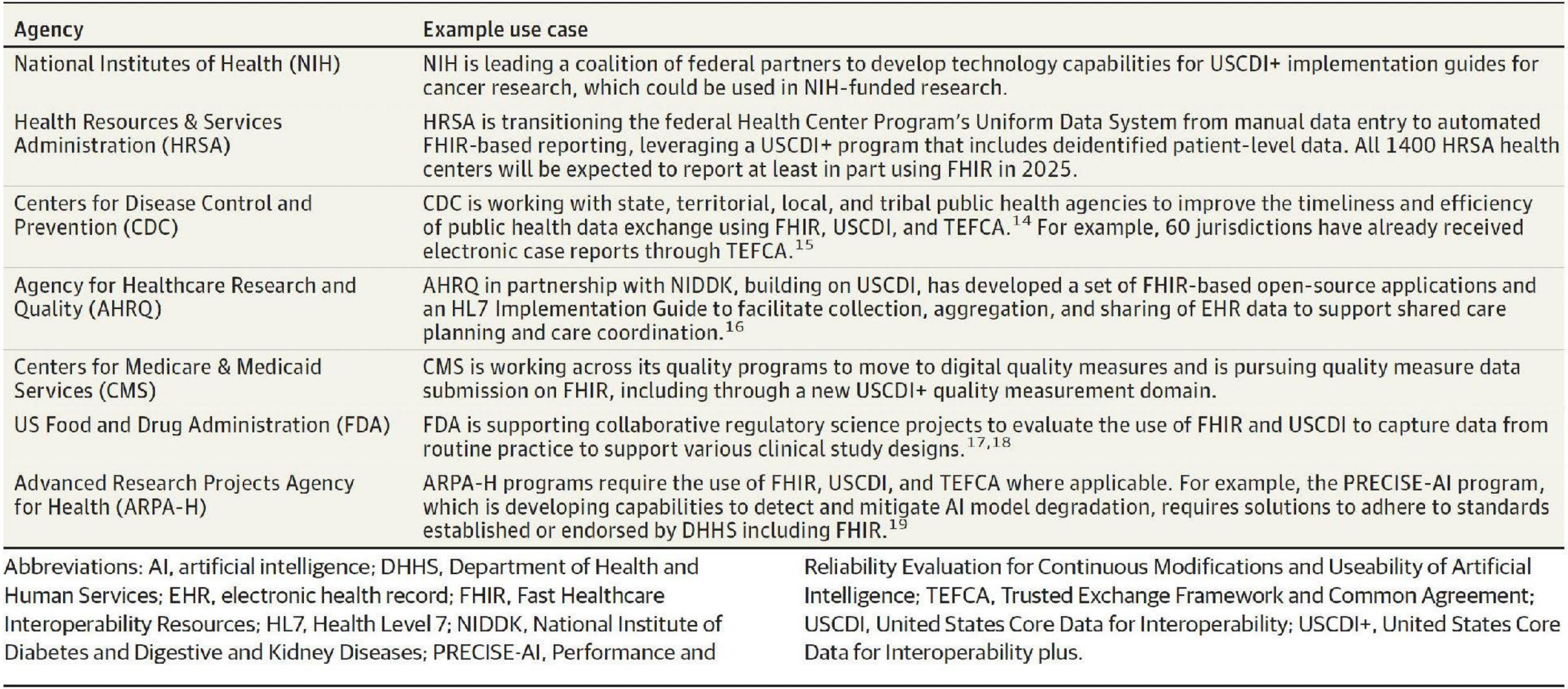


Global Context & FDA Connections

- FDA focuses on drug safety and efficacy.
- EU adds data governance frameworks like the DGA, Data Act, and EHDS.
- Ongoing dialogues aim to streamline data-sharing protocols.

Illustrative Examples of How US DHHS Agencies Are Using the Building Blocks of USCDI, FHIR, and TEFCA to Standardize the Capture, Transfer, and Exchange of Health Data

JAMA. doi:10.1001/jama.2025.0068

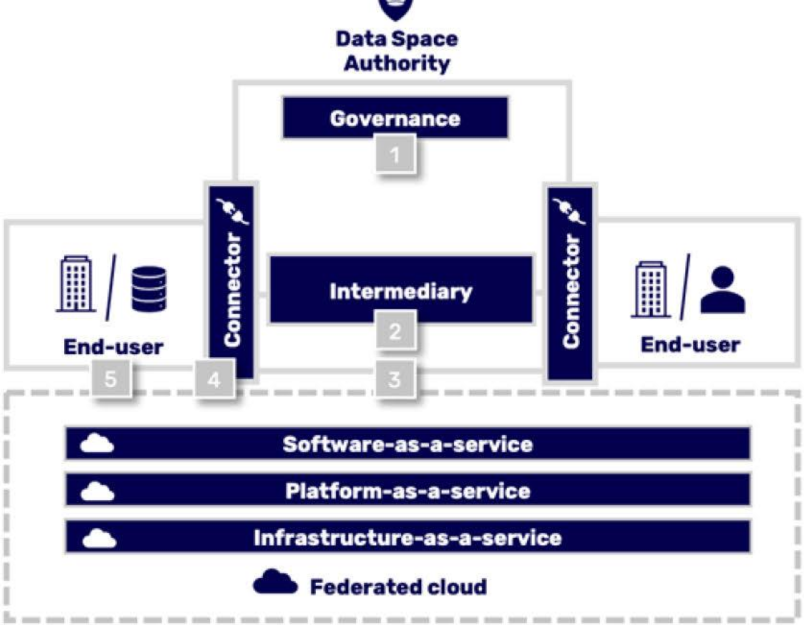


Agency	Example use case
National Institutes of Health (NIH)	NIH is leading a coalition of federal partners to develop technology capabilities for USCDI+ implementation guides for cancer research, which could be used in NIH-funded research.
Health Resources & Services Administration (HRSA)	HRSA is transitioning the federal Health Center Program's Uniform Data System from manual data entry to automated FHIR-based reporting, leveraging a USCDI+ program that includes deidentified patient-level data. All 1400 HRSA health centers will be expected to report at least in part using FHIR in 2025.
Centers for Disease Control and Prevention (CDC)	CDC is working with state, territorial, local, and tribal public health agencies to improve the timeliness and efficiency of public health data exchange using FHIR, USCDI, and TEFCA.[14] For example, 60 jurisdictions have already received electronic case reports through TEFCA.[15]
Agency for Healthcare Research and Quality (AHRQ)	AHRQ in partnership with NIDDK, building on USCDI, has developed a set of FHIR-based open-source applications and an HL7 Implementation Guide to facilitate collection, aggregation, and sharing of EHR data to support shared care planning and care coordination.[16]
Centers for Medicare & Medicaid Services (CMS)	CMS is working across its quality programs to move to digital quality measures and is pursuing quality measure data submission on FHIR, including through a new USCDI+ quality measurement domain.
US Food and Drug Administration (FDA)	FDA is supporting collaborative regulatory science projects to evaluate the use of FHIR and USCDI to capture data from routine practice to support various clinical study designs.[17,18]
Advanced Research Projects Agency for Health (ARPA-H)	ARPA-H programs require the use of FHIR, USCDI, and TEFCA where applicable. For example, the PRECISE-AI program, which is developing capabilities to detect and mitigate AI model degradation, requires solutions to adhere to standards established or endorsed by DHHS including FHIR.[19]

Abbreviations: AI, artificial intelligence; DHHS, Department of Health and Human Services; EHR, electronic health record; FHIR, Fast Healthcare Interoperability Resources; HL7, Health Level 7; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; PRECISE-AI, Performance and Reliability Evaluation for Continuous Modifications and Useability of Artificial Intelligence; TEFCA, Trusted Exchange Framework and Common Agreement; USCDI, United States Core Data for Interoperability; USCDI+, United States Core Data for Interoperability plus.

European Interplay & Potential Tensions (1 of 2)

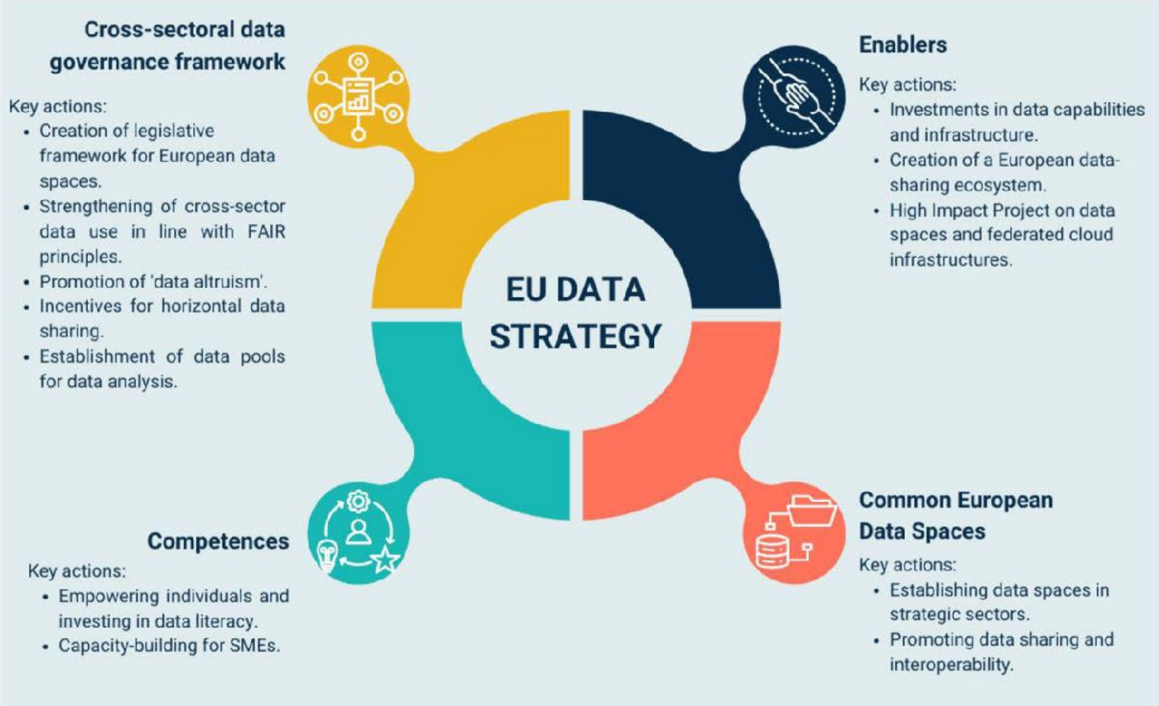
- ✓ **Shared Goals**
  - Improving patient outcomes and research innovation.
- ✓ **Governance & Collaboration**
  - Clear governance structures and collaboration can alleviate overlaps.
- ✓ **Regulatory Scope**
  - Each institution has its own specific regulatory scope.
- ✓ **Potential Friction**
  - Clinical trial data might be regulated under EMA guidelines but also require alignment with EHDS for broader sharing.



coe-dsc.nl

European Interplay & Potential Tensions (2 of 2)

- The EU data sharing landscape involves various institutions with overlapping mandates and potential conflicts.
- Synergies exist in the coordinated push for innovation and patient-centric solutions.
- However, complexities arise from differing scopes and potential conflicts in resource allocation, compliance, and duplicative requirements.



EU DATA STRATEGY

Cross-sectoral data governance framework

Key actions:
- Creation of legislative framework for European data spaces.
- Strengthening of cross-sector data use in line with FAIR principles.
- Promotion of 'data altruism'.
- Incentives for horizontal data sharing.
- Establishment of data pools for data analysis.

Enablers

Key actions:
- Investments in data capabilities and infrastructure.
- Creation of a European data-sharing ecosystem.
- High Impact Project on data spaces and federated cloud infrastructures.

Competences

Key actions:
- Empowering individuals and investing in data literacy.
- Capacity-building for SMEs.

Common European Data Spaces

Key actions:
- Establishing data spaces in strategic sectors.
- Promoting data sharing and interoperability.

dataleaders.net

UNIMORE

imi innovative medicines initiative

FACILITATE

UNIVERSITY OF MIAMI

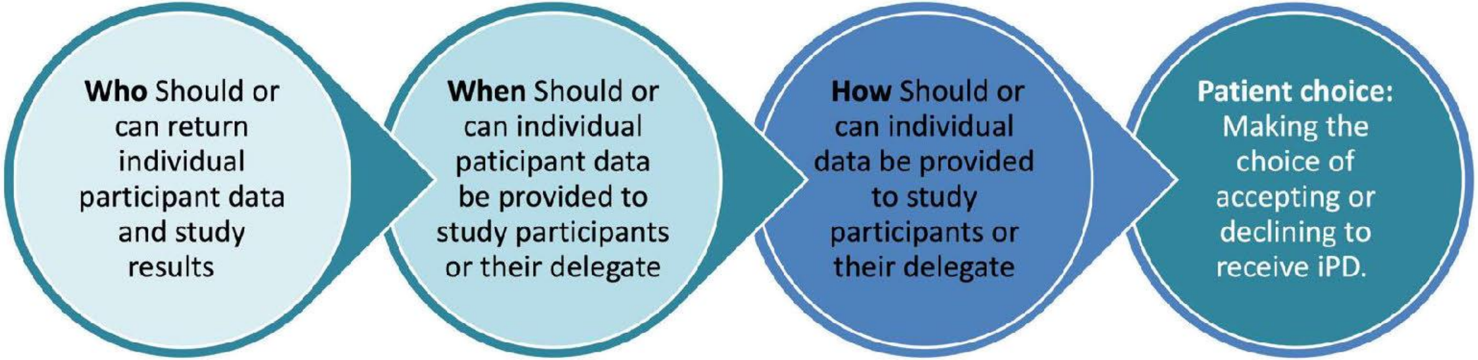
FACILITATE

Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem

To facilitate the process of patient access to clinical trial data and to manage re-use of data

Mission:

- Build a trusted, patient-centric ecosystem for ethical and legal reuse of CTs data.
- Enhance study participants' access to their health data during and after the trial.
- Develop flexible, actionable solutions for RoIPD to encourage adoption.



Who Should or can return individual participant data and study results

When Should or can individual paticipant data be provided to study participants or their delegate

How Should or can individual data be provided to study participants or their delegate

Patient choice: Making the choice of accepting or declining to receive iPD.

RoIPD = Return of Individual Participant Data.
CTs = Clinical Trials

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Ref: joan.blom@unimore.it

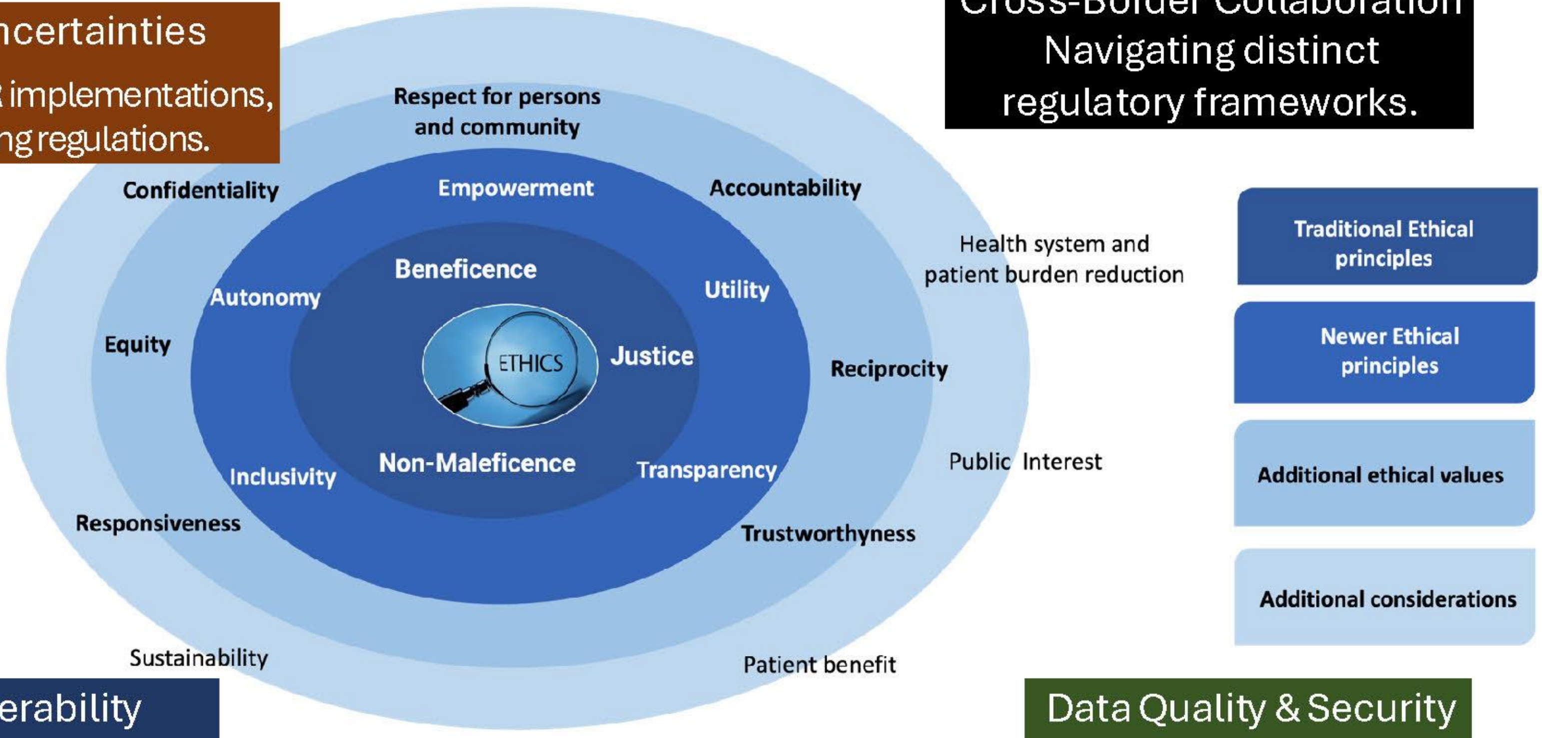
FACILITATE Challenges & Considerations

Legal Uncertainties

Varying GDPR implementations, overlapping regulations.

Cross-Border Collaboration

Navigating distinct regulatory frameworks.



Interoperability

Differing standards across EU member states.

Data Quality & Security

Ensuring data is accurate, de- identified, and secure.

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FACILITATE Horizon Target: "Simplify Complexity»

- **Achievements**
  - Ethical framework guiding the Return of Individual Participant Data
  - RoIPD by design process outlining flexible uptake by sponsors according to the individual sponsors' resources
  - Pilot study testing the ethical framework guiding RoIPD by design
- **Key Challenges**
  - Fragmented national legislative EU landscape
  - Limited Engagement with National DPAs: without clear guidance from DPAs, sponsors face challenges in determining a suitable legal framework for RoIPD.
  - EMA noted that meaningful engagement with DPAs is unlikely in the near term
- **Roadmap for 2025**
  - Iterate pilot programs and gather participant feedback.
  - Advocate for RoIPD by Design
  - Consolidate learnings, scale processes and prepare for EU adoption.
  - Finalize guidance documents facilitating uptake.
  - Extension of the FACILITATE ethical framework to data sharing

RoIPD = Return of Individual Participant Data.
DPAs= Data Protection Authorities

Ref: joan.blom@unimore.it

In conclusion, if you really want to demystify the EU Data Sharing Space please consider:

Evolving EU Landscape

DGA, Data Act, and EHDS are shaping the EU data sharing space.

Institutional Interplay

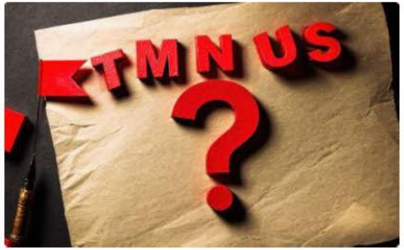
EMA, IHI, and EC are key players, with both opportunities and tensions.

Global Dimension

Coordination with FDA is crucial for bridging legal frameworks.

Action Items

Stay informed, invest in projects with compliance and interoperability.



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FACILITATE

Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem

To facilitate the process of patient access to clinical trial data and to manage re-use of data

Thank you for your attention

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If you have any questions or would like to share some feedback or criticism with us, please feel free to contact us. We would be glad to assist you.

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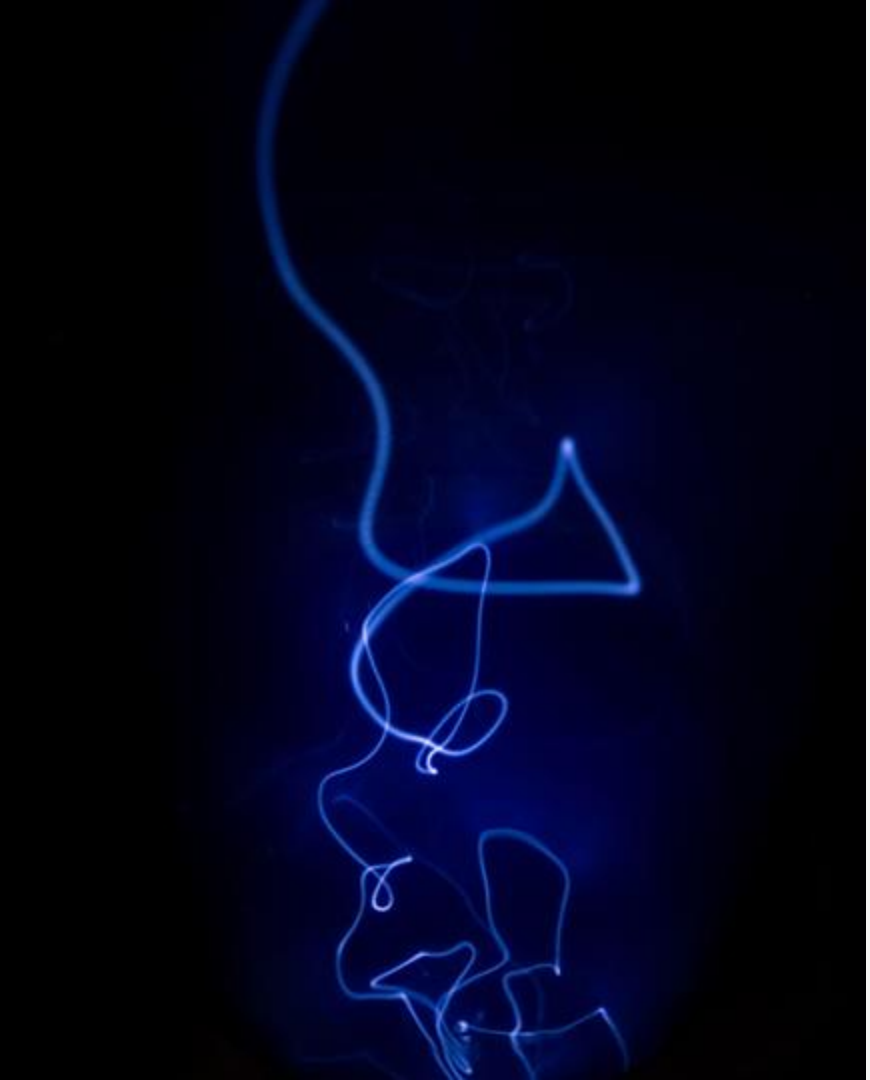
https://facilitate-project.eu/contact/



The European Health Data Space (EHDS)

29 January 2025

Tom Brookland
Regulatory Policy Lead
Pharma Development Regulatory (PDR), Basel

Disclaimers

- I am an employee of Roche
- Views expressed are of mine, on behalf of Roche and EFPIA
- I don’t work for the European Commission so will explain the EHDS as I interpret the text

Agenda

- Introduction to the EHDS
- Role of Health Data Access Bodies (HDAB)
- Pharma’s roles in the EHDS
- Policy Considerations
- Where do we go from here

Introduction: What is the EHDS and why is it needed?

The EHDS is part of the Rapidly Evolving and Connected EU Data and Digital Policy Landscape

Data Governance Act (DGA)

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

European Health Data Space (EHDS)

- Part of the Pharma Strategy for the EU
- Result of public consultation (Q1 2022)
- Draft adopted on 5 Apr. 2022

Data Act

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

Cybersecurity

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

General Data Protection Regulation (GDPR)

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

Artificial Intelligence (AI) Act

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

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

EMA/HMA Big Data Steering Group

- Focused on utilising big data to improve the regulation of medicines
- Key components include DARWIN EU, data quality framework, patient level data pilots and EMA guidance oN AI

Connected to many other EU initiatives: Revision of the EU Pharmaceutical Legislation, Europe's Beating Cancer Plan, EU Medical Devices and IVD regulations, European Digital Identity initiative, DARWIN, TEHDAS...

What is the EHDS?

First and foremost: a piece of European Legislation (legally binding i.e. it is not a choice to comply!)

More broadly defined as: an *“EU Wide health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework”*

Considered as: one of the key enablers of future innovation in Europe

Once again Europe as a first mover: as with the GDPR, EHDS will be world’s first regional data space of this size

The EHDS will be one of nine Common European data spaces created in strategic sectors and domains of public interest

A common European Health Data Space (EHDS)

The 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***

Why is the EHDS needed?

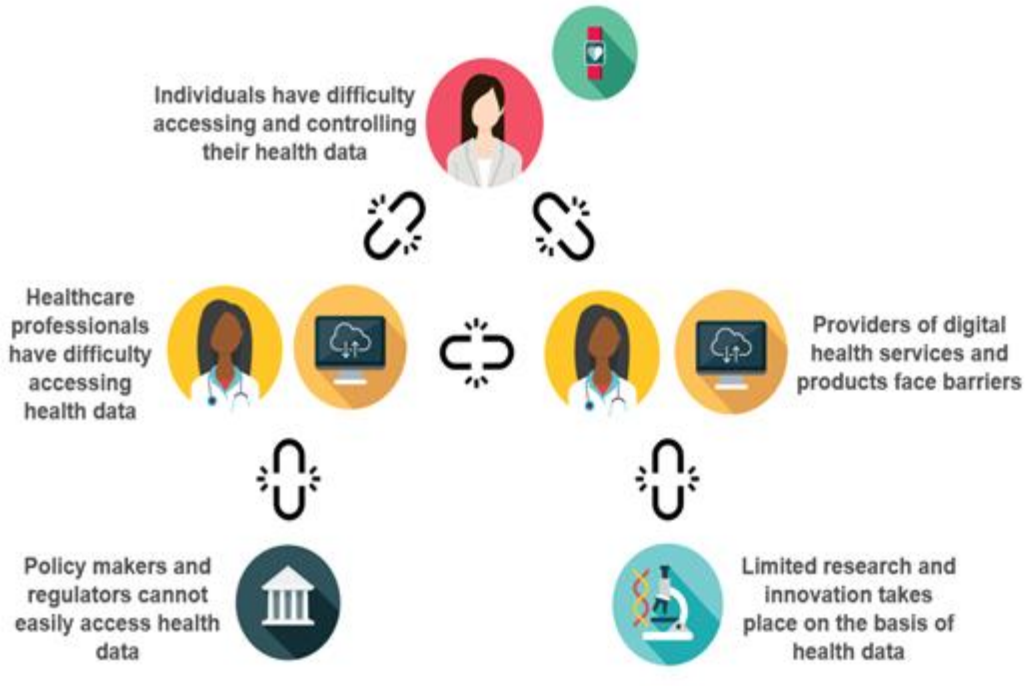


Figure 2 - Problems in controlling, using and sharing health data

Three points to note :

1. Individuals **do not have appropriate access and control** to their health data

2. **Insufficient health data exchange** negatively impacts on the direct provision of healthcare (primary use)

3. Secondary re-use of data in the EU is **very low** creating **barriers to developing and delivering healthcare innovations**

Image is an official European Commission Reference

Some Key Proposals within the Legislation

Increasing Individuals autonomy and control over their health data

- Additional rights of individuals to complement the rights provided under the GDPR in relation to their electronic health data e.g.
- Right to request an immediate copy of health record
- Right to control which HCP look at the record
- Ability to access and transfer data within the same Member State and across borders

Improving The Delivery of Healthcare through better Primary Use of data

- The MyHealth@EU is an infrastructure that enables the sharing and receiving of electronic health data processed for Primary Use (i.e., providing health services) and other supplementary health services (e.g., telemedicine and mobile health) by healthcare providers and pharmacies
- All Member States will be required to participate in this cross-border digital infrastructure for the exchange of health data for healthcare delivery

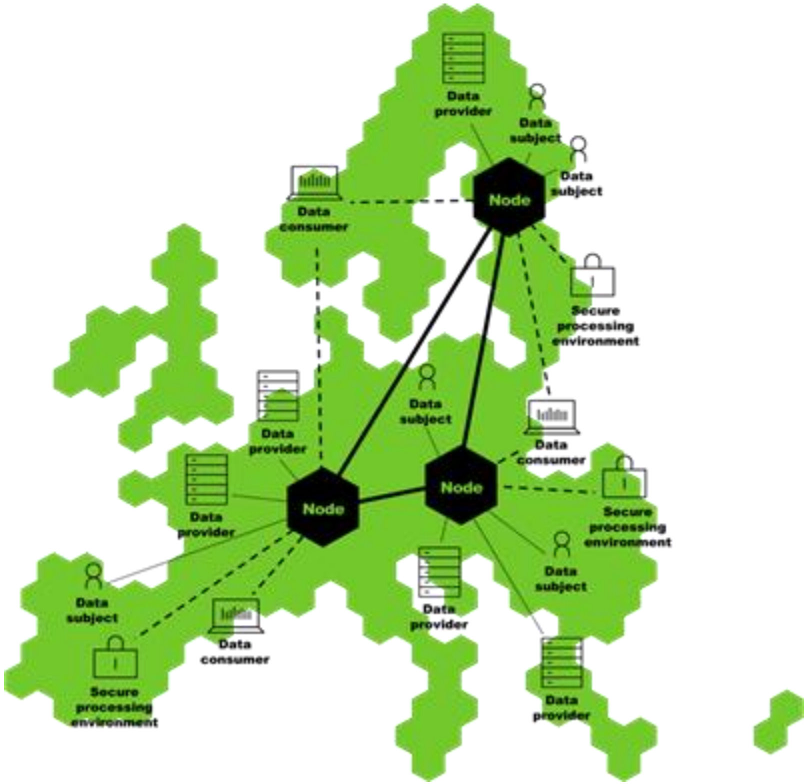
A consistent, trustworthy and efficient set-up for secondary use of health data for better R&D, innovation and policy-making

Figure 1 EHDS2 high-level architecture

- Creation of a new and decentralised EU-infrastructure for secondary use of health data (HealthData@EU)
- Mandatory set up of health data access bodies in all MS which will govern access to health data within their country
- Data access bodies to be connected as nodes in HealthData@EU
- Data users can request access to various types of health data from data holders facilitated by the data access bodies
- Permits can be granted for processing health data
- High levels of transparency

How will secondary data access work in the EHDS?
(at a high level!)

- **Health Data Access Bodies (HDAB):**
  - All EU countries will need to establish a HDAB with ability to govern access to health data within their country
  - All HDABs will connect in a new secondary use infrastructure called Healthdata@EU
  - Required to catalogue all health data sets and make searchable
- **Process for gaining access to data**
  - Data users search data catalogue
  - Data user requests access to data via permit application
  - HDAB assesses legal grounds and conditions and grants/rejects
  - If granted, HDAB works with data holder locally to curate data and provide access via secure processing environments
  - Users have 5 years to conduct research
  - Only anonymous data is provided unless access to pseudonymised data can be justified
  - HDAB will have to ensure transparency: information will be published about data access applications



Which data types are in scope for Secondary use/access?

17 categories of (broadly defined) health data

(a) electronic health data from EHRs;

(b) data on factors impacting on health, including socio-economic, environmental and behavioural determinants of health;

(ba) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

(c) pathogen data, impacting on human health;

(d) healthcare-related administrative data, including dispensation, claims and reimbursement data;

(e) human genetic, epigenomic and genomic data;

(ea) other human molecular data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;

(f) automatically generated personal electronic health data, through medical devices;

(fa) data from wellness applications;

(g) data on professional status, specialisation and institution of health professionals involved in the treatment of a natural person;

(h) population-based health data registries (public health registries);

(i) data from medical registries and mortality registries;

(j) data from clinical trials, clinical studies and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

(k) other health data from medical devices;

(ka) data from registries for medicinal products and medical devices;

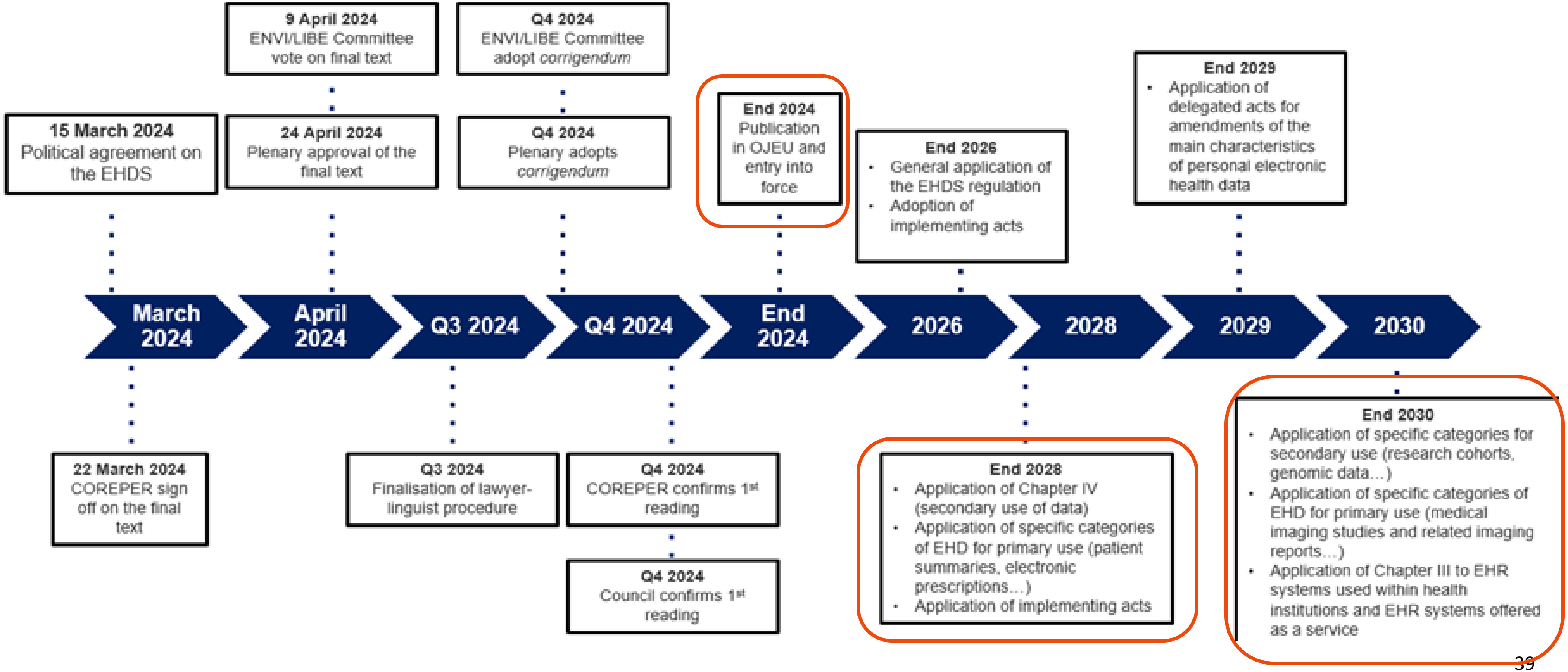
(l) data from research cohorts, questionnaires and surveys related to health, after the first publication of results;

(m) health data from biobanks and associated databases

Implementation timelines as defined in the EHDS regulation

6 years of implementation process before the EHDS is fully operational

Secondary use rules come into force in 4-5yrs time



15 March 2024
Political agreement on the EHDS

9 April 2024
ENVI/LIBE Committee vote on final text

24 April 2024
Plenary approval of the final text

Q4 2024
ENVI/LIBE Committee adopt *corrigendum*

Q4 2024
Plenary adopts *corrigendum*

End 2024
Publication in OJEU and entry into force

End 2026
- General application of the EHDS regulation
- Adoption of implementing acts

End 2029
- Application of delegated acts for amendments of the main characteristics of personal electronic health data

22 March 2024
COREPER sign off on the final text

Q3 2024
Finalisation of lawyer-linguist procedure

Q4 2024
COREPER confirms 1st reading

Q4 2024
Council confirms 1st reading

End 2028
- Application of Chapter IV (secondary use of data)
- Application of specific categories of EHD for primary use (patient summaries, electronic prescriptions…)
- Application of implementing acts

End 2030
- Application of specific categories for secondary use (research cohorts, genomic data…)
- Application of specific categories of EHD for primary use (medical imaging studies and related imaging reports…)
- Application of Chapter III to EHR systems used within health institutions and EHR systems offered as a service

What does this mean for industry?

Pharma will have Two key Roles in the EHDS (for secondary use)

1. As a Data Requester

Access health data types (faster) to help support the future discovery, development and delivery of innovative medicines, vaccines and associated health technologies

2. As a Data Holder

We will be mandated to share data we collect (including data types we currently do not share broadly)

In practical terms some requirements include….

Industry as data user

- (Once system is up and running)
  - Search health data catalogue (once live) & identify data sources we would like to access
  - Go through permit application process
  - If granted, conduct research
  - Meet transparency requirements

Industry as data holder

- (before system is up and running):
  - **Catalogue all our data sets** which meet one of the 17 health data definitions and contain EU patients
  - For each data set in scope **send a description of the data set** to relevant EU Health data access body for entry into the searchable catalogue
- (once system up and running):
  - Manage data access requests

Policy considerations

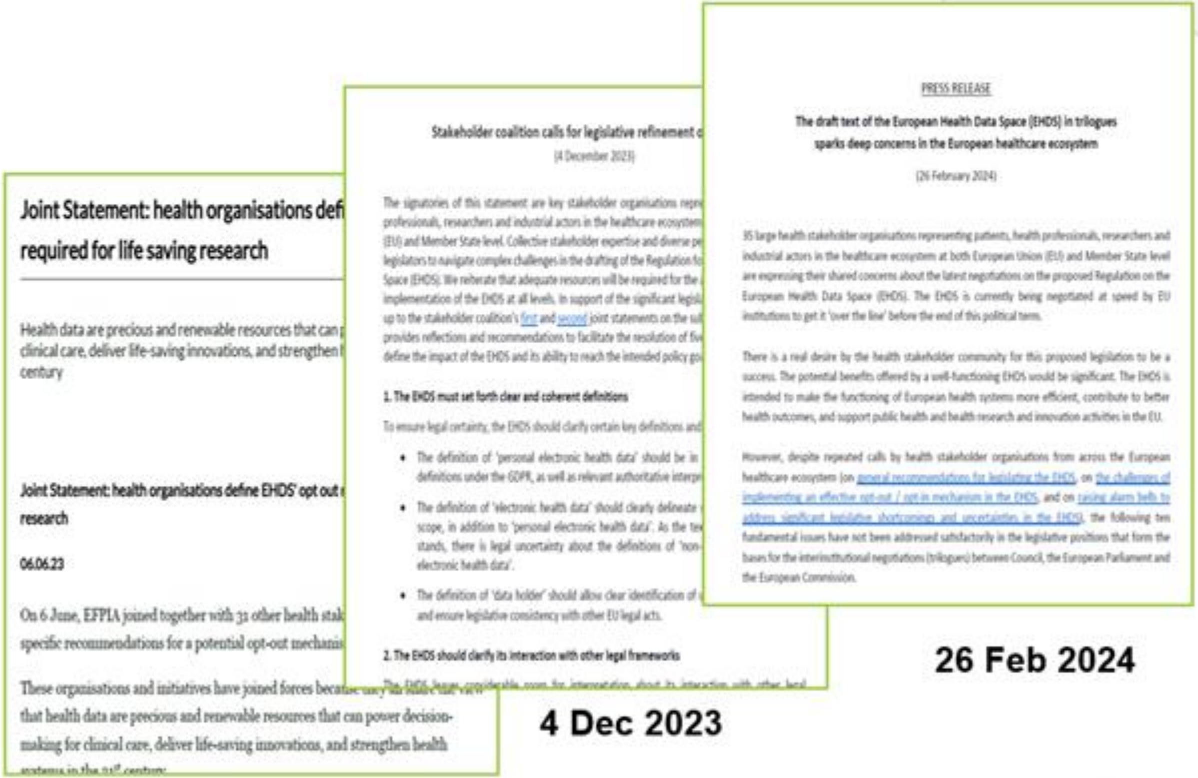
Industry Considerations Throughout the Debate

- 1. Lack of clarity on the **broad definitions** of data types in scope
- 2. Lack of clarity on the **format** of data to be shared
- 3. **IP/CCI considerations** - no time gated mechanisms could reduce incentives to conduct research in Europe
- 4. **Opt out / Opt In** mechanism - major discussion, we as industry did not see any need for additional layers
- 5. Questions over **consistency with other EU legislation** e.g. GDPR, AI Act etc. in terms of definitions and terminology etc.

As a result, many questions remain in the final text, and efforts are needed to shape so called "secondary legislation" e.g. guidance designed to help further interpret the regulation

EFPIA co-signed Multiple Joint Stakeholder Statements on the EHDS (we all want the same thing?!)

eau
ERS
european cancer
EPF
EUROPA UOMO
ELF
fertility europe
eshre
PHA EUROPE
iHD
EHA
ESC European Society of Cardiology
Biomedical Alliance in Europe
EFN
MedTech Europe
GETREAL INSTITUTE
eular
WFIPP
efpia
PASYKAF
EORTC
EHDEN
EU EYE
DIGITALEUROPE
PIONEER
EuropaBio
Alliance for Regenerative Medicine
OPTIMA
EHTEL



Joint Statement: health organisations defi
required for life saving research

Health data are precious and renewable resources that can
clinical care, deliver life-saving innovations, and strengthen
century

Joint Statement: health organisations define EHDS' opt out
research

06.06.23

On 6 June, EFPIA joined together with 32 other health stak
specific recommendations for a potential opt-out mechanis

These organisations and initiatives have joined forces beca
that health data are precious and renewable resources that can power decision-making for clinical care, deliver life-saving innovations, and strengthen health

June 2023

Stakeholder coalition calls for legislative refinement

(4 December 2023)

The signatories of this statement are key stakeholder organisations repr
professionals, researchers and industrial actors in the healthcare ecosystem
(EU) and Member State level. Collective stakeholder expertise and diverse pe
legislators to navigate complex challenges in the drafting of the Regulation fo
Space (EHDS). We reiterate that adequate resources will be required for the
implementation of the EHDS at all levels. In support of the significant legisl
up to the stakeholder coalition's first and second joint statements on the su
provides reflections and recommendations to facilitate the resolution of fiv
define the impact of the EHDS and its ability to reach the intended policy go

1. The EHDS must set forth clear and coherent definitions

To ensure legal certainty, the EHDS should clarify certain key definitions and

- The definition of 'personal electronic health data' should be in
  definitions under the GDPR, as well as relevant authoritative interpr
- The definition of 'electronic health data' should clearly delineate
  scope, in addition to 'personal electronic health data'. As the te
  stands, there is legal uncertainty about the definitions of 'non-
  electronic health data'.
- The definition of 'data holder' should allow clear identification of
  and ensure legislative consistency with other EU legal acts.

2. The EHDS should clarify its interaction with other legal frameworks

4 Dec 2023

PRESS RELEASE

The draft text of the European Health Data Space (EHDS) in trilogues sparks deep concerns in the European healthcare ecosystem

(26 February 2024)

35 large health stakeholder organisations representing patients, health professionals, researchers and industrial actors in the healthcare ecosystem at both European Union (EU) and Member State level are expressing their shared concerns about the latest negotiations on the proposed Regulation on the European Health Data Space (EHDS). The EHDS is currently being negotiated at speed by EU institutions to get it 'over the line' before the end of this political term.

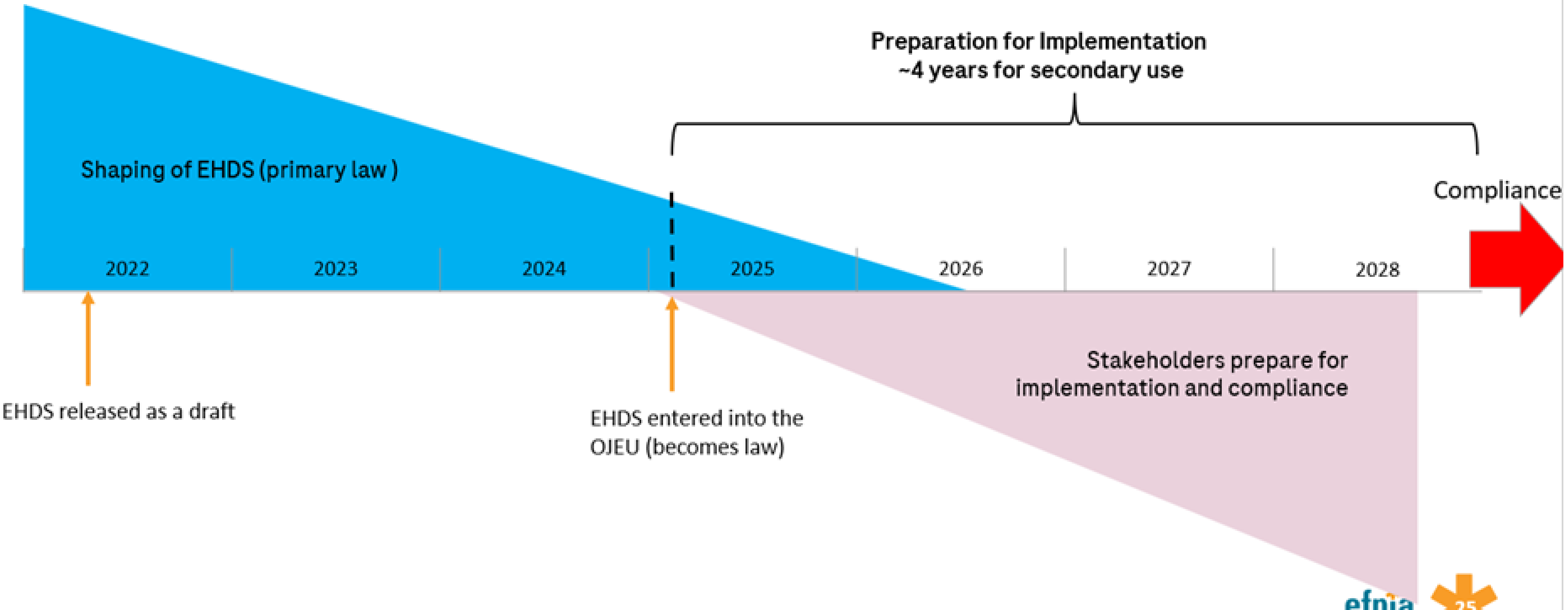
There is a real desire by the health stakeholder community for this proposed legislation to be a success. The potential benefits offered by a well-functioning EHDS would be significant. The EHDS is intended to make the functioning of European health systems more efficient, contribute to better health outcomes, and support public health and health research and innovation activities in the EU.

However, despite repeated calls by health stakeholder organisations from across the European healthcare ecosystem (on general recommendations for legislating the EHDS, on the challenges of implementing an effective opt-out / opt-in mechanism in the EHDS, and on raising alarm bells to address significant legislative shortcomings and uncertainties in the EHDS), the following ten fundamental issues have not been addressed satisfactorily in the legislative positions that form the bases for the interinstitutional negotiations (trilogues) between Council, the European Parliament and the European Commission.

26 Feb 2024

Where do we go from here?

We must now focus on 1) implementation of the Regulation



Preparation for Implementation
~4 years for secondary use

Shaping of EHDS (primary law)

Compliance

2022

2023

2024

2025

2026

2027

2028

EHDS released as a draft

EHDS entered into the OJEU (becomes law)

Stakeholders prepare for implementation and compliance

We must now focus on 2) Shaping of the secondary legislation

Public consultations

TEHDAS2 is developing guidelines and technical specifications to enable seamless use of health data across Europe under the upcoming European Health Data Space (EHDS). Each product is released for a 30-day public consultation to ensure that the final outputs meet the needs of citizens, health professionals and regulators.

1. DRAFT GUIDELINE FOR DATA HOLDERS ON DATA DESCRIPTION (Click to view more details)

2. DRAFT TECHNICAL SPECIFICATION ON THE NATIONAL METADATA CATALOGUE (Click to view more details)

3. DRAFT GUIDELINE FOR DATA USERS ON GOOD APPLICATION PRACTICE FOR DATA ACCESS AND REQUESTS (Click to view more details)

4. DRAFT GUIDELINE FOR DATA USERS ON HOW TO USE DATA IN A SECURE PROCESSING ENVIRONMENT (Click to view more details)

Upcoming public consultations

SEP-OCT 2025
TOPIC: Processes to manage permits or data pseudonymisation

Documents scheduled for public consultation(Click to view)

1. Guideline for Health Data Access Bodies on fees and penalties for non-compliance regulated to the EHDS regulation
2. Guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
3. Guideline for data holders on making personal and non-personal electronic health data available for reuse
4. Guideline for Health Data Access Bodies on the procedures and formats for data access
5. Technical specification for Health Data Access Bodies on data minimisation and de-identification
6. Technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
7. Guideline for Health Data Access Bodies on linkage of health datasets
8. Guideline for Health Data Access Bodies on obligations towards natural persons
9. Guideline for Health Data Access Bodies on data altruism in health

IPD Data Sharing in the EU

Moderator: Aaron Mann Chief Executive Officer, **CRSDA**

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Francis Crawley Executive Director, **GCPA,** Chair, **IDPC**

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CRDSA

Clinical Research Data Sharing Alliance

Thank you!

For additional resources and information, please visit:

https://crdsalliance.org/resources