WEBINAR REPORT

From Policy to Practice: EHDS Implementation to Support better Real-World Evidence for HTA/Payers

Wednesday, 9 April 2025, 15:00-16:30 CEST

Speakers

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RWD4BE multi-stakeholder initiative

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INTRODUCTION

The 9 April RWE4Decisions Webinar **"From Policy to Practice: EHDS Implementation to Support Better Real-World Evidence for HTA/Payers"** brought together a vibrant community of over 200 participants to discuss how the European Health Data Space (EHDS) could generate robust real-world evidence (RWE) to support better informed, more timely HTA/Payers decisions. The discussion focused on practical steps toward EHDS implementation, offering multi-stakeholder perspectives that included policymakers, HTA/Payers, health technology developers, patients, and clinicians. Speakers shared insights into the opportunities of secondary use of health data under the EHDS, and national and pan-European initiatives showcasing how Member States are preparing for implementation and the evolving role of RWE in shaping patient-centred decisions.

THE EHDS: ACCESSING DATA FOR SECONDARY USE

David Asturiol, Policy Officer in the "Digital Health Unit" in DG SANTE, European Commission, delivered the keynote address, providing a comprehensive overview of the **EHDS user journey** as expected in March 2029, which is the date of entry into force of the Regulation.

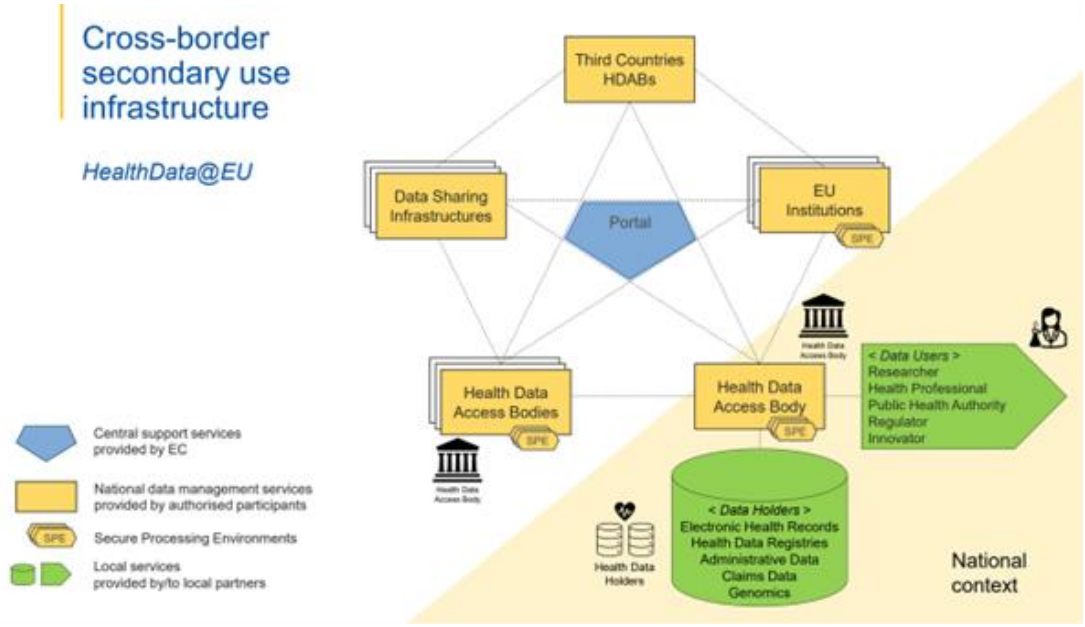
He outlined the EHDS as a cornerstone of the EU's broader data strategy, aimed at creating a common European framework for the secure and ethical use of health data across borders. For secondary use, the EHDS is designed to support purposes such as research, innovation, public health, policymaking, regulatory decision-making, and HTA, while ensuring strong legal and technical safeguards.

The current fragmentation of data access mechanisms and the administrative burden of cross-border research create barriers to effective RWE access. The EHDS aims to address these by introducing harmonised rules and infrastructures, including:

- The establishment of a Health Data Access Body (HDAB) in each Member State to manage requests and authorise access to data for predefined public interest purposes outlined in the EHDS Regulation.
- The definition of data holders who will need to describe datasets using a common standard and provide access to data upon request by HDABs.
- The inclusion of a defined list of data categories that need to be made available for reuse such as electronic health records, registries, claims, and genomic data.
- A streamlined process for requesting access to data which will allow requesting access to data from different countries with just filling one common application.
- A defined process to obtain access to datasets across the EU based on the issuance of permits which will establish the conditions under which the datasets can be accessed including by whom, for how long, and for which purpose.
- Enhanced safeguards for privacy of individuals, including data minimisation, anonymisation of data and processing in a secure processing environment.

- A transparent system in which HDABs will make public the data applications, decisions and permits, results of processing, and penalties imposed in case of non-compliance with EHDS requirements.
- The right for citizens to control their data by providing the possibility to opt-out from secondary uses.

The **HealthData@EU** infrastructure will connect all national HDABs to facilitate cross-border secondary use. To access health data, the user journey begins with data users who submit a data request to their national HDAB through HealthData@EU. If the request meets the legal, scientific, ethical, and technical requirements, the HDAB issues a data permit, specifying datasets, purposes, and conditions. The data is then made available within a secure processing environment (SPE), where it can be analysed without being downloaded or exported, ensuring privacy-by-design. The HDAB is subject to a number of transparency requirements including applications, permits, and results. This approach provides full traceability and auditability, while also supporting secondary use for defined public interest purposes without needing individual consent, under strict safeguards. The data user would be accountable for paying fees to compensate for the cost incurred by HDABs and data holders in making the data available.



The EHDS will surface several datasets that are now inaccessible and will thus enable researchers or HTA bodies in one country to access data held in another, while data itself remains securely hosted at national level. The system will include mechanisms for authentication, authorisation, and harmonised access control, with joint governance to ensure consistency and trust across Member States and ensure participation of stakeholders via the Stakeholder Forum.
As the **implementation** phase has just started, stakeholders, including HTA bodies and Payers, should start preparing for the establishment of health data access bodies, technical infrastructures, and the upcoming Implementing Acts that will define operational details.

The conclusion highlighted the EHDS as a unique opportunity to obtain timely, high-quality, and pan-European data access, which will be essential for enabling robust RWE to support better informed, faster HTA and pricing and reimbursement decisions.

FINHITS – EFFICIENT AND SECURE SECONDARY USE OF HEALTH DATA IN FINLAND

Maari Parkkinen continued by sharing practical insights from **Finland's experience** in implementing a centralised, secure health data access system, offering valuable lessons for Member States preparing for the EHDS. **Findata**, the Social and Health Data Permit Authority, is a national pioneer in health data governance, operating since 2020 under a legislative model that closely mirrors key features of the EHDS. **Findata** acts as a one-stop-shop for secondary use data requests, issuing data permits and combining datasets from multiple public and private health and social data controllers. Its focus is on enabling secure, privacy-preserving access to high-quality data for research, statistics, and official decision-making.

Finland's approach has made practical implementation challenges visible early, particularly in areas such as:

- Building trust among data controllers, researchers, and the public.
- Managing complex multi-source data requests, including data linkage.
- Ensuring data quality and metadata transparency, so users can assess whether the available data is fit-for-purpose.

It uses a SPE, where approved users can analyse pseudonymised data without it ever leaving the secure server. This "*data stays in place*" model supports GDPR compliance and aligns with the security principles envisioned in the EHDS. While Findata's experience offers a solid foundation, scaling to a European-level infrastructure through EHDS will require deeper cross-border collaboration, interoperability, and common standards. Finland is actively contributing to EU-level discussions and sees value in aligning its national system with the EHDS framework.

The **FinHITS collaborative initiative** was highlighted, aims to improve the usability of datasets relevant to HTA, particularly by improving secondary use infrastructure for secure and efficient secondary use. FinHITS also works to align metadata and documentation in a way that supports HTA-relevant research and evaluation. It is actively contributing to capacity-building for Finland's readiness to connect to future EHDS infrastructures: FinHITS is not only supporting national needs, but also helping Finland engage in EU-level collaboration, making it easier to scale its solutions and practices to the EHDS context.

In closing, Maari encouraged fellow Member States to start early, engage with users, and adopt an iterative learning approach to implementation. Effective EHDS deployment depends not only on legislation, but on operational readiness, trust, and a shared commitment to secure, high-quality data reuse in the public interest.

THE HEALTH OUTCOMES OBSERVATORY (H2O)

Dr. **Jørgen Schøler Kristensen**, chair of the **Pan-European Observatory (PEO)** in the **Health Outcomes Observatory (H2O)** presented the real-world challenges and opportunities in implementing the EHDS to enhance healthcare delivery, especially through better integration of Patient Reported Outcomes (PROs) perspectives into RWE.

He began by reflecting on years of work by stakeholders engaged in shaping the EHDS, noting growing efforts to return meaningful information to both patients and healthcare systems. The challenges were addressed through the lens of four primary stakeholder groups:

1. **Patients**, who increasingly want their voices to be heard and to receive high-quality care, as well as getting greater control over their data.
2. **Healthcare providers**, who face structural challenges such as staff shortages and an aging population, but still aim to contribute to research and innovation.
3. **HTA agencies** and the European Medicines Agency (EMA), which are grappling with the accelerated approval of new therapies that often enter the market with limited evidence but high cost.
4. **Pharmaceutical companies**, who also recognise the growing need for robust data, particularly data related to patient quality of life, which is often underrepresented in clinical evaluations.

While electronic health records (EHRs) across Europe contain a wealth of clinical data, they often lack structured and usable data about quality of life, a gap that significantly undermines the real-world applicability of new therapies. Integrating the patient voice, particularly through standardised and scalable methods, could fill this gap and directly inform HTA processes, reimbursement decisions, and treatment optimisation.

An **example from Denmark** was presented, where HTA authorities assess new drugs that are clinically promising but difficult to implement due to insufficient supportive data. These situations reflect broader systemic challenges: new treatments often enter the market based on expedited approvals with sparse data, leaving national bodies to make difficult decisions without clear evidence of benefit in real-world contexts.

Future healthcare decisions must be more patient-centric, data-informed, and collaborative. Dr. Jørgensen advocated for deeper integration of PROs and RWE into decision-making frameworks and encouraged EU-level initiatives like EHDS to support these aims structurally and consistently.

REFLECTIONS FROM BELGIUM: RWD4BE

Ingrid Maes shed light on **Belgium's national initiative on real-world data (RWD4BE)**, focusing on how the country is building a future-ready healthcare system through structured multi-stakeholder collaboration. The initiative, supported and co-chaired by Jo De Cock, seeks to enable the secure reuse of RWD for various critical purposes, including improving quality of care, advancing research, supporting reimbursement decisions, and promoting economic and ecosystem development. The initiative's core objective is to provide an enabling governance framework for data reuse, emphasising privacy, structure, and quality. This governance model is being built through bottom-up engagement with hospitals and care providers, aimed at preparing them to deliver reusable, structured, and high-quality data. Several action groups have been established to support this effort, focusing on practical implementation at the clinical level.

To operationalise this framework, Belgium has conducted two **pioneering pilot projects**:

1. **CAR-T for multiple myeloma**: This pilot focused on collecting clinically relevant data from clinicians in an automated and simplified way. The goal was to make the data available for both reimbursement purposes and broader research applications.
2. **Advanced Therapy Medicinal Products (ATMPs) for rare diseases**: This included therapies for Duchenne muscular dystrophy and haemophilia. These cases, although extreme in their complexity, served as stress tests for the framework.

From these pilots, Belgium has been able to derive key structural tools, including:

- A **decision tree** to guide the selection of core data elements, responsibilities, and data governance protocols. This tool clarifies roles across all involved stakeholders (clinicians, patients, registry holders, and policymakers) and determines who is responsible for data access, analysis, and reporting, and serves as input for the **RWD Collection Collaboration Agreement**, a multi-partite agreement amongst all involved parties.
- A **preparedness playbook**, a foundational guide for hospitals and research entities to be ready for RWD re-use. It ensures that collection practices are standardised and aligned with the overarching goals of the initiative.

RWD4BE is not merely academic or theoretical, but is built around practical, scalable tools and models that could be applied as a blueprint for all other cases and by other European countries, to support cross-border collaboration, as the EHDS takes shape.

In closing, Ingrid Maes reinforced the importance of interdisciplinary collaboration, co-development with all-involved parties (clinicians, payers, registry holders hospitals, patients, companies), and transparent data governance to support healthcare system preparedness that is not only data-driven but also equitable and responsive to emerging scientific and therapeutic evolutions.

REFLECTIONS FROM THE INDUSTRY: EUCOPE

Alexander Natz, Secretary General of the **European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)** delivered a policy-focused intervention that underscored the strategic importance of RWE in shaping both innovation of treatments for rare diseases and the evolving European HTA and regulatory landscape. He positioned RWE as central to Europe's competitiveness in the global biopharmaceutical sector, particularly within the framework of the newly adopted EHDS legislation.

The EHDS is not only a legal instrument but a competitive enabler. This digital infrastructure can help Europe close the innovation gap with other regions, particularly in industries such as pharmaceuticals, biotechnology, and medical technology. US-based pharma and biotech companies expressed a growing interest in how Europe is advancing both the EHDS and its RWE strategy, giving an indication that the EU's approach is attracting international attention.

Focusing specifically on rare diseases, RWE is indispensable for identifying and addressing data gaps, particularly in HTA. In these often under-researched therapeutic areas, clinical trial data are frequently limited or absent, making RWD essential for comprehensive evaluations. These challenges will be strengthened within the newly launched EU HTA regulation, especially in initial areas of focus like oncology and ATMPs.

Alexander Natz concluded by stressing the importance of keeping the EHDS implementation simple, acknowledging the inherent challenges due to the need for data interoperability. From an industry perspective, the ideal solution would be a pan-European registry involving stakeholders from multiple countries. Citing the existence of a single HTA system and a joint clinical assessment report, he argued that a unified European registry is both logical and achievable.

PANEL DISCUSSION

A **panel discussion** followed, where the speakers responded to the following questions asked by the audience:

- What do you see as the biggest challenge in implementing the EHDS, and how do we overcome it?
- Can countries outside the EU provide their data and use the EHDS?
- What EHDS deliverables can we expect to see in four years?
- What is the one thing you want the audience to remember and act on from today's session?

A number of important **learnings** followed from this conversation. Firstly, a broad recognition emerged that **harmonisation** across Member States is not merely a technical necessity but a strategic imperative. Without alignment in terminology, data standards, and legislative procedures, the promise of the EHDS could be undermined by inconsistency and inefficiency. Panellists also highlighted the importance of **multi-stakeholder involvement**, arguing that successful implementation will require sustained engagement from industry, regulators, academia, clinicians and patient representatives.
Secondly, **early action** is of great importance. Although the full implementation of the EHDS is still several years away, there is already substantial groundwork being laid. Stakeholders must seize this moment to contribute to pilots, invest in infrastructure, and help shape governance mechanisms while they are still in development. **Transparency and trust** were also recurring themes throughout the discussion. As patient data becomes increasingly central to healthcare innovation, safeguarding privacy and ensuring ethical data use must remain a top priority.

Finally, **industry perspectives** must not be sidelined. The current regulatory burden, characterised by fragmented demands from various national and EU bodies, was described as unsustainable. A more integrated and efficient regulatory environment will be necessary to support both the practical implementation of the EHDS and the broader goal of maintaining Europe's competitiveness in the life sciences sector.

Final conclusions focused on what panellists wanted the audience to remember and act on about the EHDS implementation, leading to insightful **takeaways**:

- The successful implementation of the EHDS will depend on **building trust** through inclusive and transparent governance structures that clearly define how data is accessed and used across borders.
- **Practical, real-world use cases** should guide the development of EHDS frameworks, ensuring that the system is grounded in reality and delivers tangible value to patients, providers, and policy- and decision- makers alike.
- **Regulatory coherence** is essential: current fragmentation creates inefficiencies that risk undermining innovation. Harmonisation across national and EU-level processes will be critical to streamline efforts and reduce unnecessary burdens.
- **Ethical use of patient data** must remain a core principle. As the foundation of real-world evidence, patients' contributions deserve recognition, and systems must be designed to ensure their data is handled with transparency, integrity, and respect.
- All **stakeholders** must commit to ongoing collaboration and remain agile as the EHDS evolves, recognising that its success will require not only technical solutions but shared responsibility and continuous dialogue.

RWE4Decisions REAL WORLD EVIDENCE

RWE4Decisions is a payer-led multi-stakeholder learning network, which has developed **stakeholder actions** that will better enable the use of real-world evidence in HTA/payer decisions about highly innovative technologies.

The work has been commissioned by the Belgian National Institute of Health and Disability Insurance (NIHDI) and is led by a multistakeholder **Steering Group** with a wider community of contributors including HTA bodies and payers, regulatory agencies, patient groups, clinicians, industry, analytics experts and academic experts/researchers.

The RWE4Decisions Secretariat is provided by FIPRA, with sponsorship in 2024 by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Astellas, AstraZeneca, Gilead, MSD, Roche and Takeda.

For further information and to watch the recording of the webinar, visit our **website**.

What are you are doing to progress learnings on the use of RWE?

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