



**World
Physiotherapy**

Europe region

**Guidance document -
Impact of the European Health Data
Space (EHDS) on Physiotherapy
Practice in the Europe Region**

Advocacy and EU Matters Working Group (A&EUMWG)

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**GUIDANCE DOCUMENT - IMPACT OF THE EHDS ON PHYSIOTHERAPY PRACTICE IN THE EUROPE
REGION**

Europe Region
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INTRODUCTION

The European Health Data Space (EHDS) Regulation (EU) 2025/327 represents a shift in healthcare data governance across the European Union. Entered into force on 26 March 2025, the regulation establishes a harmonised legal and technical framework for safe, efficient cross-border sharing and reuse of electronic health data. Its dual aims are to empower EU citizens with control over their health data and to enable secure secondary use (research, innovation, policymaking) while maintaining rigorous privacy protections aligned with the General Data Protection Regulation (GDPR).

As the regulation progresses through phased implementation from 2027 to 2035, all health professionals, including physiotherapists, will experience substantial changes to how patient data is accessed, documented, exchanged, and protected.

Physiotherapists serve as health data holders (when creating patient records) and as data users (when accessing records or participating in research). Understanding the European Health Data Space obligations, opportunities, and uncertainties is essential for physiotherapy associations and individual practitioners to prepare adequately.

This document examines the European Health Data Space regulation, clarifies physiotherapists' roles and responsibilities, identifies areas of uncertainty requiring further guidance, and provides practical recommendations for national physiotherapy associations, individual practitioners and academia in preparing the profession for EHDS implementation.

It is based on the information currently available and will require updating and refinement as further regulatory guidance, technical specifications, and implementation details become known.

1. SUMMARY

The European Health Data Space (EHDS), established by Regulation (EU) 2025/327, is a groundbreaking EU regulation aimed at improving the quality and continuity of care (including cross-border care) by:

- Giving citizens more control over their electronic health data (more specific and enforceable than the GDPR).
- Enabling secure and uniform exchange of medical data between healthcare providers when data are available electronically. Data must be recorded in a uniform way.
- Allowing secure secondary use of health data for research, policy and innovation.
- Regulating the EU market for Electronic Healthcare Records (HER) systems.

The EHDS entered into force on 26 March 2025 and will be implemented in phases between 2027 and 2035.

Physiotherapists, like other healthcare providers, are affected by the EHDS through the primary (clinical care) use of data and through secondary use of data when they act as data holders or data users. The regulation does not specifically target the profession of physiotherapy, but creates obligations and opportunities linked to how health data is accessed, shared and governed.

2. SCOPE AND RELEVANCE OF THE EUROPEAN HEALTH DATA SPACE FOR PHYSIOTHERAPY

2.1 Core EHDS Concepts

The EHDS distinguishes two principal types of health data use:

- **Primary use:** The use of electronic health data for direct clinical care (including diagnosis, treatment and care coordination), including across borders.
- **Secondary use:** The use of health data for research, policymaking, public health, statistics, innovation and regulatory activities, under strict governance and permit frameworks.

Physiotherapists interact with primary health data as part of clinical care. If a physiotherapy practice collects, updates or uses electronic patient health records (EHRs), these actions fall under EHDS provisions. The EHDS does *not* create new professions-specific licensing requirements but standardises data exchange processes independent of profession.

2.2 Applicability to Physiotherapists

Under the EHDS, any health professional involved in creating or accessing electronic health records or other health datasets is considered a health data user when accessing data for care delivery. This includes physiotherapists when they:

- Access a patient's EHR for care continuity, treatment planning, or assessments.
- Enter or update clinical information in a certified EHR system.
- Request cross-border access to patient records (e.g., when treating EU citizens from other member states).

Physiotherapists do *not* become subject to EHDS solely by virtue of belonging to the profession; rather, applicability depends on engagement in electronic data processes governed by the regulation.

2.3 Physiotherapy-Specific Scenarios Under EHDS

Scenario 1. Primary use, within-country care across professionals

Situation: A patient starts physiotherapy for subacute low back pain. They have also seen a general practitioner and later an orthopaedic specialist.

EHDS-enabled data flow:

- The physiotherapist receives a digital referral. The data from the referral are entered into the physiotherapy EHR.
- Central patient consent for data exchange is checked via the EHR.
- The physiotherapist accesses relevant electronic health data via the national health professional access service (for care delivery).
- The patient restricts access to a sensitive item (for example, a past diagnosis) while keeping the rest available.
- Information from the physiotherapy EHR becomes available to other health professionals and to the patient.
- The patient can see who accessed their data, when, and which data were accessed.
- If the restriction creates a safety risk, emergency access can be permitted and must be logged.

Why it matters for physiotherapy: Better medication and history visibility supports safe treatment decisions. Administrative burden will be reduced. Direct Restriction and auditability require clear member guidance.

Scenario 2. Primary use, cross-border rehabilitation episode

Situation: A Swedish resident fractures an ankle while travelling in Portugal. Acute care happens in Portugal. Rehabilitation continues in Sweden.

EHDS-enabled data flow:

- Portuguese clinicians access the Patient Summary for safe treatment, including allergies, medications, and medical history.
- ePrescription and eDispensation reduce reliance on paper prescriptions.
- Under EHDS, Patient Summary and ePrescription services should be operational in all Member States by 2029. Other categories (for example imaging, lab results, discharge reports) should follow by 2031.

Why it matters for physiotherapy: Cross-border access improves continuity and reduces duplicated tests. Rehabilitation content risks being underrepresented unless mapped into patient summary and discharge structures nationally.

Scenario 3. Secondary use, multicentre rehabilitation effectiveness study

Situation: A university and three rehabilitation services in different Member States study real-world outcomes after stroke rehabilitation.

EHDS-enabled data flow:

- Researchers apply for access through national Health Data Access Bodies. Access is granted only under a data permit or approved request.
- Data are accessed in a secure processing environment with controlled identities, audit logs, and restrictions on downloading person-level data.
- Re-identification is prohibited. Outputs must be anonymised, and results should be made public within the Regulation's timelines.

Why it matters for physiotherapy: Creates a scalable route to multicountry effectiveness evidence, but only if rehabilitation variables are captured consistently and are discoverable via national holders.

Scenario 4. Secondary use, health economics and policy advocacy

Situation: A National Physiotherapy Association partners with a public health institute to assess whether earlier physiotherapy reduces imaging, opioid use, and downstream costs in musculoskeletal care.

EHDS-enabled data flow:

- The project applies for secondary use under policymaking and related public-interest purposes.
- Analysis occurs in a secure processing environment. Only anonymised outputs are released.
- HealthData@EU supports secondary use infrastructure via national contact points for secondary use.

Why it matters for physiotherapy: Supports reimbursement and workforce arguments with system-level evidence, while keeping governance and privacy controls explicit.

3. KEY IMPACTS ON PHYSIOTHERAPY PRACTICE

3.1 Improved Access to Patient Information

Cross-border records: EHDS infrastructure (e.g., through MyHealth@EU) enables physiotherapists to access essential patient summaries, e-prescriptions and other priority data categories across EU member states, subject to patient consent and national procedures.

Continuity of care: Physiotherapists can obtain more complete medical histories, reducing duplicative assessments and supporting integrated care planning.

3.2 Standardisation and Interoperability Requirements

EHR conformity: EHR systems used in healthcare settings, including physiotherapy practices, must comply with EHDS interoperability, security, and certification standards. This requirement ensures consistent data formats and cross-system operability.

Logging and traceability: Systems must log access and use of health data transparently, enabling patients and authorities to see who accessed which data and when.

3.3 Administrative and Professional Responsibilities

Data governance compliance: Physiotherapists must adhere to EHDS rules when accessing or processing patient data within EHR systems. This includes respecting patient rights (e.g., access restrictions, opt-outs) under EHDS aligned with GDPR.

Training needs: As systems evolve, physiotherapists will require adequate training on EHDS-enabled data exchange platforms and patient data rights.

4. AREAS OF UNCERTAINTY AND IMPLEMENTATION CHALLENGES

Despite EHDS being adopted, numerous uncertainties remain, particularly relevant to frontline health professionals:

4.1 Operationalisation of Primary Use Across Borders

Unclear workflows: Detailed procedural guidance on how physiotherapists request, receive and update cross-border medical records is still under development, pending implementing acts and technical standards.

Semantic interoperability: Differences in clinical terminologies (e.g., physiotherapy-specific assessment terms) across national systems could limit the meaningful use of exchanged data. Implementation pilots and standard mapping approaches are still evolving.

Expected clarity: A series of implementing acts and technical standards due by March 2027 are anticipated to provide more granular guidance and tools.

4.2 Responsibilities and Liability for Data Accuracy

There is limited clarity on professional responsibilities when data from other providers or countries are incomplete or contain discrepancies. How professional liability applies to data interpretation remains subject to national health law and ethical codes as well as future guidelines.

4.3 Secondary Use Participation

Physiotherapists may participate as health data users or holders in secondary use projects. Small physiotherapy practices (fewer than 10 employees and an annual turnover of less than €2 million) are, in principle, exempt from the obligations as a data holder, unless national legislation provides otherwise. Details about how practices engage with national Health Data Access Bodies (HDABs) are still being clarified. National rules on fees, permit processes, and technical requirements will vary.

Expected clarity: Member states developing guidance in cooperation with the European Commission via HealthData@EU infrastructure pilots will issue more precise procedures by 2027–2029.

5. NATIONAL FLEXIBILITIES AND MEMBER STATE DECISION LATITUDE

EHDS is directly applicable law across the EU but certain elements allow national discretion:

5.1 Opt-Out and Access Restrictions

- a) Restriction of access (primary use):** EHDS gives individuals the right to limit or block access by healthcare professionals to specific parts of their electronic health data for care purposes, within a common EU framework and further detailed by Member States. At the same time, the system ensures that essential data can still be accessed in emergencies through “break-the-glass” mechanisms, with proper logging and accountability.
- b) Opt-out (primary use):** EHDS does not introduce a general EU-wide opt-out from the use of health data for care. Instead, it focuses on fine-grained access controls that allow people to manage who can see which data. Member States may introduce broader opt-out rights, as long as these do not undermine continuity, safety, and quality of care.
- c) Opt-out (secondary use):** EHDS does not create a mandatory EU-wide opt-out from the secondary use of electronic health data (e.g. for research, innovation, or policymaking). Member States may choose to introduce opt-out mechanisms for certain types of secondary use under national law. The Regulation mainly relies on strong governance, transparency, purpose limitation, data minimisation, and clear procedures for handling citizens’ rights.

5.2 Organisational Implementation of Health Data Authorities

The establishment and detailed functioning of national Digital Health Authorities and Health Data Access Bodies (HDABs) are subject to national law design, within the EHDS framework. How these bodies operate can impact physiotherapy practices seeking to engage with secondary use requests.

5.3 Integration with National EHR and eHealth Systems

The way EHDS standards are integrated with pre-existing national eHealth laws and infrastructures (e.g., digital health records mandates, reimbursement data flows) is determined by Member States, leading to variations in national implementation timelines and operational procedures.

6. GOVERNANCE & NATIONAL PHYSIOTHERAPY ASSOCIATIONS REPRESENTATION

EHDS obliges Member States to designate digital health authorities and to consult relevant stakeholders, including health professional associations. National Physiotherapy Associations should proactively leverage this framework to secure a formal role in national EHDS implementation, influencing decisions on professional access services, guidance, and eHealth infrastructure to protect professional interests and patient safety.

7. RECOMMENDATIONS FOR KEY ACTIONS FOR THE EUROPE REGION

The Europe Region of World Physiotherapy should explore the possibility to coordinate a shared European approach to EHDS implementation. The aim is to reduce fragmentation across Member Organisations and ensure that physiotherapy data are represented consistently across countries and systems. This coordinated approach should complement, not replace, national implementation work. This could include three linked streams of action:

7.1 Semantic and terminology convergence

Develop a common physiotherapy semantic and terminology strategy, designed for multilingual use and national adaptation, without diverging concept definitions.

7.2 Minimum dataset

Develop a minimum dataset to provide insight into the quality and effectiveness of physiotherapy care and to monitor developments, enabling data from different European countries to be combined.

Promote and encourage data sharing among all physiotherapists across Europe, fostering a culture of collaboration that supports benchmarking, learning, and continuous improvement of care.

7.3 Coordinated engagement with EU governance and implementation programmes

Coordinate engagement with EHDS governance structures and with implementation resources provided by the European Commission, including the EHDS Platform and the HealthData@EU ecosystem. This should focus on securing visibility for physiotherapy requirements in EU-level implementation.

Together, these actions provide Member Organisations with shared resources that they can use to engage national authorities and national implementation programmes in a coherent way, reducing the risk of a patchwork of incompatible solutions.

8. PRACTICAL GUIDANCE FOR NATIONAL PHYSIOTHERAPY ASSOCIATIONS

1. Monitor EHDS implementing act developments scheduled through 2027 and beyond.
2. Engage with national Digital Health Authorities to align professional training and EHR system compliance.
3. Collaborate on interoperability and terminology standards relevant to physiotherapy data types.
4. Prepare guidance for practitioners on consent, opt-outs, and patient data rights under EHDS.
5. Explore roles in secondary data use initiatives via national HDABs where relevant.
6. Check legal aspects regarding implementation at National Level.

8.1 Key Actions for Physiotherapy Associations in the EHDS Era

Physiotherapy Practices

- Confirm the EHDS compliance status of your current EHR system with the vendor and obtain a roadmap for achieving full certification.
- Evaluate and allocate budget for potential system upgrades or migration, aiming for readiness by March 2027.
- Appoint a staff member as an “EHDS Champion” to monitor regulatory developments, coordinate internal training, and serve as the point of contact for digital health initiatives.
- Initiate planning for cybersecurity and data protection enhancements to ensure secure handling of electronic health data.

Physiotherapy Researchers and Academics

- Participate in or establish national physiotherapy research networks focused on secondary use of health data.
- Identify priority research questions that address rehabilitation effectiveness, equity, and integration of care.
- Develop research proposals that leverage EHDS secondary use infrastructure, ensuring compliance with governance and ethical requirements.
- Collaborate with international partners to design cross-border studies on rehabilitation effectiveness and health economics at the EU level.

9. CONCLUSION

The EHDS Regulation is not merely a compliance burden to be managed. It is a strategic opportunity that physiotherapy must explore, as it creates a shared European framework for primary and secondary use of electronic health data. For physiotherapy, the benefits depend on the extent to which national implementations and European exchange formats capture clinical reasoning, functioning, goals, interventions, and outcomes relevant to physiotherapy in a reusable way.

Many technical details and professional workflows remain under development, with major clarity expected by 2027–2029 as implementing acts and national guidance mature.

Without coordinated semantic interoperability work, implementation risks converging to a minimum common denominator that limits the visibility of physiotherapy contributions. A shared semantic and implementation approach is vital, alongside support to Member Organisations for national engagement, to ensure physiotherapy is represented consistently and credibly across Europe.

This approach will strengthen professional autonomy, advance evidence-based practice, support preventive person-centred care, and enhance overall physiotherapeutic patient care across Europe.

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