European Health Data Space (EHDS) Implementation in Greece

Establishing an EHDS stakeholder ecosystem

A policy White Paper informed by national multi-stakeholder workshops and EU implementation experience

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Prepared jointly by the Hellenic Cancer Federation - ELLOK, the Pharma Innovation Forum and i-HD – the European Institute for Innovation through Health Data.

Based on national multi-stakeholder workshops and European implementation experience.

Foreword

The European Health Data Space (EHDS) marks a new phase in Europe's digital health transformation. For Greece, it represents both a regulatory obligation and a strategic opportunity to modernise the health system, strengthen patient and citizen trust and unlock the value of health data for care, research and public policy.

Greece enters this phase with important strengths, including significant progress in nationwide digital public services and health information infrastructures. At the same time, the transition to a data-driven health system requires addressing persistent challenges related to interoperability, data quality, governance, and trusted data reuse. Meeting these challenges will require more than technical readiness. It calls for effective coordination across institutions, meaningful engagement of stakeholders, and shared learning on how health data can be used responsibly and effectively.

This white paper proposes a practical approach: establishing a structured stakeholder ecosystem to complement institutional governance and support Greece in translating EHDS into real benefits for citizens, patients, healthcare professionals and innovators.

Executive Summary

The European Health Data Space (EHDS) establishes a common European framework for the primary use of electronic health data to support patient care and for the secondary use of health data for research, innovation, public health and policy-making. This has significant tranformative implications for national health systems, public authorities, hospitals and other healthcare providers and data users. Institutional arrangements alone will not be sufficient. Effective secondary use depends on high-quality, semantically consistent data and trusted access pathways that respect patients' rights and preferences. Without these foundations, Greece risks achieving formal EHDS compliance without delivering meaningful value from health data.

Greece is progressively establishing the institutional and technical foundations required for EHDS implementation under the policy leadership for health data of the Ministry of Health and for horizontal digital infrastructure, interoperability frameworks and digital identity services of the Ministry of Digital Governance.Key operational roles are played by national actors that already support large-scale digital health services, while investment is underway in infrastructures for secondary use and AI-enabled health applications. Together, these elements provide the backbone for regulatory compliance, cross-border primary use and the gradual operationalization of secondary-use services. For Greece, EHDS is therefore both a challenge and an opportunity. Challenges include tight timelines, uneven digital maturity and interoperability gaps. Opportunities include building trust, improving coordination and maximizing the value of health data nationally and across Europe.

This white paper synthesizes two national multi-stakeholder workshops held in 2025 and examines how Greece can complement formal governance with a structured stakeholder ecosystem including mechanisms for sustained patient and citizen engagement, co-design and transparency, supplemented by contextual analysis and implementation experience of current European models for stakeholder consultation. It focuses on how Greece can advance the implementation of EHDS in an effective and credible manner by complementing the emerging institutional framework, led by public authorities, with a structured stakeholder ecosystem

Institutional arrangements alone are not sufficient to address the more complex challenges associated with EHDS. Without proper stakeholder engagement, alongside enabling policy and new structures, EHDS implementation, especially concerning the secondary use of data, will be at risk.

Institutional arrangements alone are insufficient: Effective secondary use depends on high-quality, semantically consistent data that are fit for purpose and trusted by professionals, innovators, and citizens. Challenges such as heterogeneous clinical representations, fragmented coding practices, and uneven data quality remain largely national responsibilities. Without strong foundations, there is a risk of formal EHDS compliance without meaningful data reuse; issues that fall largely within national responsibility and cannot be fully regulated at EU level. Their impact is high

as without strong semantic and data quality foundations, there is a risk of achieving formal EHDS compliance without delivering high-value data use and reuse, especially to healthcare providers that will be called upon to carry a significant part of the responsibility for compliance.

The white paper proposes the establishment of a complementary stakeholder ecosystem to support EHDS implementation, particularly for secondary use, through coordination, shared learning and structured feedback to public authorities. This ecosystem would focus on coordination, shared learning, voluntary alignment and implementation pilots in areas best addressed through—stakeholder engagement, while remaining fully aligned with the institutional framework led by public authorities. The paper concludes with proposed actions and targeted recommendations addressed to health authorities and relevant stakeholder groups.

Recommendations to the Ministry of Health

Recommendation 1. Endorse a complementary and autonomous EHDS stakeholder ecosystem

The Ministry should officially support the creation of a national stakeholder ecosystem. The endorsement should clarify its purpose/scope and recognise that it operates independently of formal regulatory or decision-making functions, while actively integrating patient organisation input and perspectives.

Recommendation 2: Establish a strategic alignment interface without operational control

The Ministry should create a light interface to align national EHDS priorities with ecosystem activities. It would share policy context, timelines, priorities and receive structured input, without controlling the ecosystem's work programme or outputs.

Recommendation 3: Provide financial support for a neutral coordination and facilitation function

Targeted funding should support a small, neutral office to coordinate meetings, document outputs and ensure transparency, without directing content or conclusions. This support should cover activities such as convening stakeholders, supporting workstreams logistically, documenting outputs, ensuring continuity and facilitating patient and citizen engagement.

Recommendation 4: Establish formal channels for communicating priorities to the ecosystem

Clear mechanisms should allow ministries to communicate regulatory milestones and implementation needs while preserving ecosystem autonomy. These channels should support timely alignment while preserving the ecosystem's autonomy in determining how to respond to identified priorities.

Recommendation 5: Establish formal channels for receiving and processing ecosystem input

The Ministry should establish structured mechanisms for receiving, acknowledging, and processing input from the ecosystem, including technical insights, implementation feedback, and identified risks. These mechanisms should ensure that ecosystem contributions are considered in policy preparation and implementation planning, without creating binding commitments or expectations of adoption.

Recommendation 6: Commit to transparency in how ecosystem input is used

The Ministry should provide feedback on how the ecosystem input is used, including where such input informs policy, guidance, or implementation decisions and where it does not. This feedback loop is essential to maintaining trust, credibility and sustained engagement, while preserving institutional accountability.

1. Why a White Paper?

For Member States (MS), EHDS is not a distant policy vision but an imminent implementation reality. The Regulation introduces concrete obligations, defined timelines and new institutional roles, notably for data holders, data users and national authorities responsible for health data access. At the same time, EHDS challenges existing national health information systems, many of which have evolved in fragmented ways, shaped by local priorities, legacy infrastructures and uneven levels of digital maturity.

Across the EU, Member States increasingly recognize that effective EHDS implementation (especially for secondary use) requires more than formal institutional arrangements. While regulatory compliance is ensured through designated authorities and infrastructures, many countries complement these with structured stakeholder engagement mechanisms to address practical challenges such as trust and acceptance, data quality, technical and semantic interoperability, market preparedness and operational feasibility. The maturity levels across MS vary significantly; however organized, governed and transparent national stakeholder consultation is a common practice across the majority of MS. These approaches reflect a shift away from one-off stakeholder consultations toward more durable ecosystem models that support learning, coordination and trust over time.

Experience across Member States suggests that stakeholder engagement is most effective when it is:

- √ *structurally anchored, rather than purely ad hoc;*
- √ *focused on concrete implementation challenges, not general debate;*
- √ *linked to institutional decision-making through clear interfaces; and*
- √ *designed to support learning and trust-building over time.*

Current practice illustrates a shift away from one-off stakeholder consultations towards more durable ecosystem approaches that complement formal EHDS governance. They provide useful reference points for Member States seeking to balance legitimacy, autonomy and effectiveness of EHDS implementation progresses.

Across the EU, Member States increasingly recognize that effective EHDS implementation - especially for secondary use - requires more than formal institutional arrangements. Some Member States have institutionalised stakeholder participation within national health data platforms. **France**, for example, has embedded stakeholder representation directly into the governance of its national health data infrastructure, providing continuity, legitimacy, and structured input into strategic and operational decisions. Other countries, such as the **Netherlands**, have adopted infrastructure- and agreement-based models that combine public investment with broad stakeholder participation around shared services, standards, and governance frameworks.

Many MS are also organising stakeholder engagement around the emerging functions of Health Data Access Bodies, through advisory groups, communities of practice and pilot-oriented collaboration. These mechanisms are often complemented by time-limited consultations and workstreams linked to concrete implementation outputs, rather than open-ended dialogue. Examples of HDAB-centred stakeholder engagement can already be observed in countries such as **Finland, France, Belgium, Germany** and the **Netherlands**, where advisory groups, communities of practice and pilot-oriented collaboration are being used to prepare access procedures, secure processing environments, metadata standards and communication approaches in line with EHDS. These approaches help ensure that access procedures, secure processing environments and metadata standards are not only compliant, but workable and predictable for both data holders and legitimate data users.

The two multistakeholder workshops explored how Greece can move beyond minimum regulatory compliance and build a sustainable national ecosystem for EHDS implementation. The workshops brought together representatives from public authorities, healthcare providers, researchers, patient organisations, industry and technical experts. Beyond focusing on regulatory interpretation, discussions centered on practical implementation challenges, trust and public support, ecosystem roles, and the conditions required for EHDS to function effectively in the Greek context, a context characterized by both demonstrated strengths and persistent structural gaps.

Greece has shown a strong capacity to deploy nationwide digital public services when there is clear political ownership, centralised operational responsibility and sustained investment. Over the last decade, several large-scale digital health services have achieved broad adoption and become embedded in daily practice. The national ePrescription and eReferral services operated by IDIKA, illustrate that complex health information infrastructures can be successfully implemented and maintained at national scale. More recently, citizen-facing services such as the myHealth application, accessible through gov.gr, have expanded transparency and usability by enabling individuals to view and interact with selected health data digitally. The strategic role of the Ministry of Digital Governance and the wider national digital transformation agenda, further provide an enabling backdrop for EHDS implementation through cross-government interoperability, identity and access management and a growing culture of digital-by-default public services. Building on these strengths provides an opportunity to extend digital maturity from service delivery to high-quality data reuse, supporting evidence-informed decisions across care, research and health policy.

The white paper builds directly on EU experiences and the outcomes of these workshops, translating workshop insights into a coherent national perspective on how an EHDS ecosystem could be shaped in Greece. It articulates a shared vision, identifies key actors and enablers and proposes priority actions that can support effective, trusted and value-driven implementation of EHDS, in line with European requirements and national realities.

2. Why Is EHDS2 Implementation Challenging in Greece?

Greece's readiness is asymmetric. The country has advanced key primary use services, while large-scale secondary use remains structurally underdeveloped. This asymmetry reflects differences in maturity between data exchange for care and data reuse for broader public interest purposes. EHDS2 requires not only access and procedures, but semantic consistency, robust governance, and systematic data quality. These elements are essential to ensure that health data are fit for purpose and can support robust evidence generation for regulatory, public-health and policy-making decisions. Without these foundations, compliance risks formalism rather than value. In this context, the challenge extends beyond technical implementation to ensuring meaningful and trustworthy data reuse at scale.

The asymmetry is particularly evident when contrasting Greece's relatively advanced cross-border primary use with its more limited preparedness for large-scale secondary use. While progress is being made in establishing institutional roles and technical infrastructure, the country remains structurally under-prepared in areas that are critical for large-scale data reuse. EHDS secondary use depends not only on access mechanisms and procedural compliance, but also on semantic foundations, data governance and systematic data quality processes that preserve clinical meaning across contexts.

More specifically, chapters II and III of the EHDS Regulation (EHDS1) govern the primary use of electronic health data. They focus on enabling individuals and healthcare professionals to access and exchange priority health data for care purposes, while ensuring enforceable patient rights to access, control and share their data. EHDS1 is supported by secure cross-border exchange mechanisms, strengthened security and logging requirements, and obligations on EHR systems to implement harmonised interoperability and transparency features, notably through the European Electronic Health Record Exchange Format (EEHRxF), which enables consistent implementation across Member States.

To date, many Member States (including Greece) have implemented exchange of Patient Summaries and ePrescriptions through their National Contact Points for eHealth, although coverage, completeness and operational maturity vary across care settings. The additional obligations introduced by EHDS1 primarily concern the requirement for healthcare providers to import and export priority health data in the EEHRxF; to implement strengthened security, access control and authentication mechanisms; to maintain audit logs with patient visibility and to operationalise patient rights to access, receive and share their electronic health data. Baseline data quality requirements are intended to ensure that exchanged EEHRxF data can be safely and meaningfully used in practice. Overall, EHDS1 compliance is operationally demanding but not the primary systemic risk for Greece.

The main risks affecting EHDS1 success are well known and largely operational in nature: procurement delays, legacy system constraints, budgetary pressures, uneven digital maturity across providers and the capacity of vendors and hospitals to deliver changes within the regulatory timelines. Overall, while EHDS1 compliance entails non-trivial investment and operational effort, it is unlikely to represent the primary systemic risk for EHDS implementation, which in fact lie with the implementation of EHDS2.

EHDS2 presents the greatest implementation challenge, as it depends on semantic interoperability, data quality and governance elements that remain largely national responsibilities. Chapters IV–VI of the Regulation (EHDS2) address the secondary use of electronic health data for public interest, research, innovation, policy-making and regulatory purposes under a harmonised EU framework. EHDS2 encompasses a much broader range of health data and richer data sets, therefore raises significant semantic interoperability and data quality challenges that cannot be addressed by the EEHRxF alone, due to its limited data scope. Without strong semantic and data quality foundations, there is a risk of achieving formal EHDS compliance without delivering high-value reuse.

Properly and timely addressing these challenges will not only secure the operationalization of the EHDS2, but will also increase confidence in the data exchanged through the EEHRxF, thereby enhancing trust and usability for primary use.

Beyond data infrastructure, methodological capacity to generate robust real-world evidence will be equally important for high-value secondary use

EHDS2 encompasses a much broader range of health data and therefore raises significant semantic interoperability and data quality challenges. While Greece is currently strengthening its institutional foundations for EHDS implementation, the development of a structured, durable stakeholder ecosystem remains an opportunity to complement formal governance with sustained coordination, learning, and trust-building—particularly for secondary use.

3. A stakeholder Ecosystem to Support EHDS Implementation

The purpose of the stakeholder ecosystem is not representation or consultation, but problem-solving: to reduce EHDS implementation risk by addressing issues that cannot be resolved through regulation alone.

The national institutional framework required for EHDS implementation provides the formal mandates, governance authority, and core technical infrastructures necessary to comply with the Regulation, including cross-border primary use and the establishment of national secondary use services. A stakeholder ecosystem can play a decisive role in enabling EHDS to function in practice. By complementing the institutional ecosystem with a transparently governed stakeholder platform, Greece can reduce the risk of achieving formal EHDS compliance without meaningful data use and reuse.

The following sections outline how such a stakeholder ecosystem could be organised, how it would interact with institutional actors and what priority actions would be required to make it effective.

3.1. Stakeholders to Participate in the EHDS Stakeholder Ecosystem

The stakeholder ecosystem supporting EHDS2 should be deliberately broad, while remaining purpose-driven and problem-focused. Participation should be defined not only by institutional mandate, but by the ability of actors to contribute perspectives, skills, and commitments that are critical for high-value secondary use of health data.

The following non-exhaustive list of participants were identified as a complementary ecosystem around the institutional EHDS framework. Their perspectives, skills, and commitments provide the practical and societal foundations needed for EHDS to move beyond procedural compliance and deliver reusable, trustworthy health data. Many actors may play more than one role within the ecosystem (for example, university hospitals as both healthcare providers and research organisations).

The subsections below examine the perspective and benefits to each stakeholder individually, which is important to consider. It is,however important to note that these benefits are interdependent and mutually reinforcing. The benefits can only be realised by the aligned actions of multiple stakeholders in parallel. There is no single “first mover” who can initiate a chain of actions. This is indeed the definition of an ecosystem.

Patient and citizen organisations

Role

Central to trust in both EHDS1 and EHDS2 they represent patient interests in access, control, transparency, and rights under EHDS1 and provide perspectives on acceptability, public benefit, safeguards, and communication under EHDS2.

Contribution

They engage continuously in co-designing ethics and transparency mechanisms and offer input into risk and benefit assessment frameworks.

Value

Their involvement strengthens accountability, clarifies safeguards and ensures that health data use delivers tangible societal benefit. Effective EHDS2 implementation depends not only on technical and governance foundations, but also on sustained engagement of patient and citizen organisations, whose input helps ensure that data reuse is trustworthy, ethically sound and socially valuable.

Public authorities and public-interest users *(payers, policy units, HTA bodies, public health institutes)*

→ Public authorities have a role in both EHDS1 oversight and EHDS2 value creation perspectives.

→ For EHDS1, their interests focus on compliance, service continuity, patient rights enforcement, and system resilience. For EHDS2, they bring a population-level and policy perspective, ensuring that secondary use supports public value objectives.

→ They benefit from more timely, comparable, and interpretable data to support planning, evaluation, and policy design

Healthcare providers and care networks *(public and private hospitals, healthcare providers, diagnostic centres)*

→ Healthcare providers are the primary generators of clinical data and therefore play a decisive role in EHDS implementation. Their interests centre on meeting timely compliance requirements for both EHDS1 and EHDS2, continuity of care, manageable implementation costs and trust in exchanged information.

→ Providers bring clinical context, operational realism and insight into how data are captured in practice, which is essential for data quality at source.

→ Their participation will support alignment of local practices with nationally agreed approaches.

→ In return, providers benefit from improved trust in data reuse, feedback loops that enhance clinical documentation, and evidence generation that supports healthcare quality improvement and service planning to improve outcomes and reduce wastage.

Professional bodies and scientific societies *(medical associations, nursing bodies, laboratory and radiology societies)*

→ Professional bodies play a cross-cutting role across EHDS1 and EHDS2.

→ For EHDS1, they are critical for clinician acceptance of data exchange, interpretation of exchanged information and trust in cross-border care scenarios. For EHDS2, they

contribute clinical credibility, guidance on semantic interpretation, and pathways for professional engagement.

→ Their involvement supports uptake of data quality and interoperability practices.

→ In return, they gain influence over how clinical meaning is preserved and reused.

Registry operators and disease-specific data holders (*national and regional registries, screening programmes, public health surveillance systems)*

→ These stakeholders are primarily interested in the secondary use, contributing curated datasets, domain expertise, and experience with longitudinal data governance.

→ Their involvement supports alignment between routine care data and registries, reducing fragmentation and duplication.

→ They benefit from improved interoperability, clearer legal and operational frameworks for reuse, and greater visibility and impact of the data they steward.

Research organisations and academia *(universities, research institutes, clinical research centres)*

→ Research organisations are key secondary data use interested parties,

→ They bring methodological expertise, requirements for fitness-for-purpose data for regulatory, HTA, public health and research uses, and experience with ethical and scientific governance.

→ Their commitments include articulating reuse needs, contributing to standards. good practices and evidence-base, and engaging responsibly with access procedures.

→ They play a limited role in EHDS1 implementation but indirectly benefit from improved quality and consistency of primary-use data as EHDS2 foundations mature. In return, they gain more predictable access to high-quality datasets and reduced transaction costs for multi-source and cross-border research.

Technology providers and data service organisations *(EHR vendors, interoperability service providers, analytics platforms)*

→ Technology providers are critical enablers of EHDS1 compliance and EHDS2 scalability.

→ For EHDS1, EHR vendors have legal obligations to implement EEHRxF requirements, security, logging and audit features and therefore bring deep insight into implementation constraints, timelines and cost drivers.

→ For EHDS2, they contribute technical expertise and scalable solutions for data processing, curation and reuse.

→ In return, they benefit from clearer requirements, greater interoperability alignment and a more predictable environment for developing EHDS-aligned solutions and addressing international markets.

Pharmaceutical industry and life sciences innovators

→ Pharmaceutical and life sciences innovators are primarily relevant to EHDS2, where they contribute expertise in evidence generation across clinical development, post-authorisation studies, outcomes research, and pharmacovigilance.

→ They bring advance methodological expertise in real-world evidence and substantial operational experience in multi-source and cross-country data use, including in support of regularoty and HTA decision-making

→ While they play no direct role in EHDS1 implementation, they benefit indirectly from improvements in primary-use data quality, interoperability and consistency.

→ As secondary data users operating under EHDS safeguards, they can contribute to evidence that supports better use of medicines, improved patient outcomes and more sustainable healthcare systems.

Data protection, ethics, and governance experts

→ These experts provide cross-cutting support to both EHDS1 and EHDS2, bringing legal, ethical, and organisational expertise essential for lawful and socially acceptable data use.

→ For EHDS1, they support interpretation of patient rights, access controls, and transparency obligations. For EHDS2, they contribute to governance frameworks, safeguards, and risk mitigation.

→ Their involvement strengthens legitimacy and reduces implementation uncertainty.

Catalytic agency/convenor

To ensure the stakeholder ecosystem functions effectively, Greece would benefit from a dedicated facilitative body, potentially a Ministry-supported but operationally independent agency or a a neutral convenor from the public-private sphere. This catalytic agency would coordinate stakeholders, support continuity and ensure patient and citizen representation in thematic workstreams and decision-support activities. Its role would be strictly facilitative rather than directive, without exercising regulatory, operational or decision-making authority. Such independence and facilitation are essential to maintain trust, promote sustained engagement and avoid conflicts of interest while enabling high value secondary use of health data.

Such an ecosystem would bring together a wide range of stakeholders around shared objectives related to high-value data reuse. By doing so, it can support the institutional framework in areas where coordination, shared learning and voluntary alignment are essential but cannot be achieved through regulation alone.

4. Structure and Governance of the EHDS Stakeholder Ecosystem

4.1. Governing Principles

The workshops and background analysis converged on the view that any stakeholder ecosystem supporting EHDS implementation in Greece must be *lightweight, purpose-driven and clearly complementary* to the formal institutional framework led by public authorities. Its value lies in enabling stakeholder coordination, shared learning, and problem-solving across a diverse set of actors whose contributions are essential for EHDS readiness.

EHDS Stakeholder Ecosystem Principles

- √ ***Complementary to institutions:*** *Supports public authorities with evidence and expertise without duplicating or replacing formal mandates.*
- √ ***Purpose-driven and problem-focused:*** The ecosystem should be governed by **clear mandate**, transparent rules of engagement and documented outputs
- √ ***Voluntary participation with clear commitments:*** *Engagement is based on expertise and contribution, with explicit expectations and responsibilities.*
- √ **Inclusiveness balanced with effectiveness**: broad participation is encouraged, but working groups remain manageable and goal-oriented
- √ ***Transparent and accountable processes:*** *Operates with clear objectives, visible outputs, and openness to scrutiny.*
- √ ***Sustainable, proportionate and aligned:*** *Relies on realistic resourcing, demonstrated value and alignment with existing initiatives, avoiding duplication and fragmentation..*
- √ ***Supportive of responsible innovation:*** *Enables research and innovation under EHDS while safeguarding ethics, data protection, and legitimate interests.*
- √ ***Patient and citizen perspectives*** *are explicitly included, ensuring the ecosystem remains responsive to societal expectations and ethical considerations.*

Whereas institutional actors have responsibility for regulatory interpretation, compliance, formal decision-making, and accountability, the role of the ecosystem is advisory and enabling; it provides structured input, practical feedback, and evidence-informed options that can inform institutional decisions.

From a decision-maker perspective, the value of the stakeholder ecosystem lies in its ability to provide timely, structured input into concrete implementation questions, without creating additional governance layers. Interaction should be organised through clearly defined interfaces, where the ecosystem responds to policy-relevant questions with concise option papers, pilot results, and risk assessments aligned to decision timelines. This enables authorities to draw on collective expertise while retaining full responsibility for policy and regulatory choices.

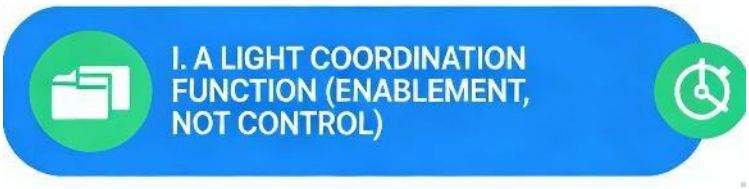
To remain effective, the stakeholder ecosystem should be explicitly problem-driven, time-limited, and output-oriented. Activities should be organised around concrete EHDS implementation challenges (particularly those related to secondary use) rather than broad thematic discussions or representational participation.

The ecosystem should maintain a structured but non-hierarchical relationship with decision-makers providing an independent space for shared learning, feasibility testing, and early identification of implementation risks.

Relevance is ensured through clearly defined interfaces—such as targeted briefings, option papers, and pilot feedback—rather than continuous oversight or control. This approach preserves institutional authority while enabling the ecosystem to contribute practical insight and evidence that reduces implementation risk.

4.2. Structure and Organisation of the EHDS Stakeholder Ecosystem

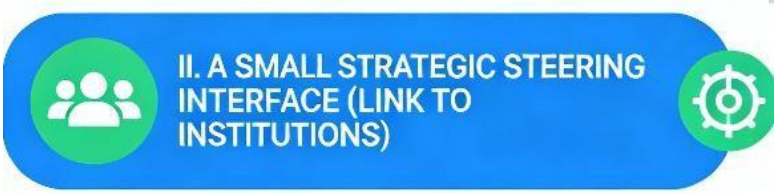
The proposed EHDS stakeholder ecosystem should be organised as a **lightweight, purpose-driven coordination structure**, while remaining flexible, inclusive and operationally effective. It should avoid becoming either a purely informal network or a parallel decision-making body.



A small **coordination and facilitation function** is essential to keep the ecosystem operational. The function supports collaboration and continuity but does **not** own content, outcomes or decision-making authority

- **Responsibilities**
  - Organise meetings and workstreams
  - Support documentation and synthesis of outputs
  - Ensure transparency and continuity
  - Act as a neutral broker between stakeholders and institutions

This role can be hosted by a trusted neutral organisation or consortium with transparent governance and conflict-of-interest safeguards, rather than a ministry.



At the core of the ecosystem should be a **strategic steering interface**, providing a formal but limited connection to public authorities responsible for EHDS implementation. Close operational learning loops with the future national Health Data Access Body will be particularly important for EHDS2 readiness.

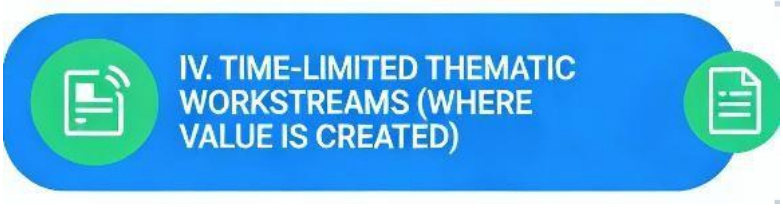
- **Role**
  - Align ecosystem priorities with national EHDS policy objectives.
  - Signal upcoming policy needs, regulatory milestones, and decision timelines.
  - Receive and consider ecosystem outputs, without exercising operational control.
- **Composition**
  - Representatives from the Ministry of Health and the Ministry of Digital Governance.
  - Observers or liaison roles from key national operators (e.g. IDIKA, future HDAB).
- **Rationale:** institutions guide on what is needed, but how or by whom work should be done. Control over ecosystem activities stays with the ecosystem

The ecosystem should include a **broad stakeholder assembly**, that provides legitimacy, diversity of perspectives, and transparency.

- **Role**
  - Set shared priorities within the ecosystem's mandate.
  - Validate work programme directions.
  - Serve as a forum for information exchange and trust-building.
- **Participants**
  - Healthcare providers and care networks
  - Professional bodies
  - Patient and citizen organisations
  - Research and academia

- Public-interest data users
- Technology providers
- Pharmaceutical and life sciences actors
- Ethics, legal, and data governance experts
- Other experts as appropriate

- **Operation**
  - Meets periodically (e.g. annually or biannually).
  - Not a decision-making body



The operational heart of the ecosystem should consist of **time-bound thematic workstreams**, each focused on a clearly defined EHDS implementation challenge.

- **Typical focus areas**
  - Specific EHDS1 implementation challenges
  - Data quality and fitness-for-purpose
  - Semantic interoperability and mappings
  - Dataset readiness for EHDS2
  - Secure processing environments and access workflows
  - Patient and public engagement in secondary data use, including transparency, opt-out and trust-building mechanisms
  - EEHRxF implementation and vendor coordination
  - Audit logging, access control and patient-visibility requirements
  - Transparency Portals
  - EHDS Communication
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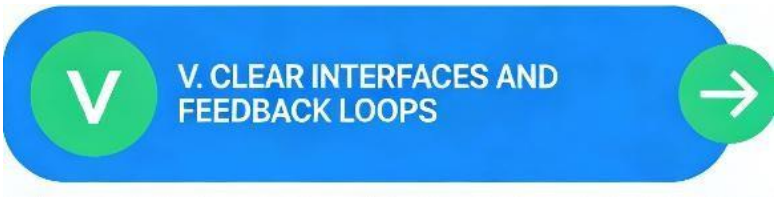
- **Characteristics**
  - Clear objectives and deliverables
  - Defined duration
  - Voluntary participation based on expertise
  - Outputs documented and reusable



Implementing the Ecosystem: First 180 Days

To ensure the ecosystem delivers actionable outputs and sustained engagement, a phased implementation plan is recommended:

- **Within 60 days** – Designate a neutral coordination function and publish the ecosystem charter.
- **Within 120 days** – Launch 2/3 time-limited workstreams, e.g.:
  - Data quality & semantic interoperability
  - Access workflows
  - Transparency & trust mechanisms
- **Within 180 days** – Deliver option papers and pilot-ready outputs, incorporating formal institutional feedback on usefulness and next steps.

This phased approach reinforces credibility, transparency, and sustainable engagement while providing a clear, implementable pathway for high-value data reuse.

5. Funding and Sustainability of the EHDS Stakeholder Ecosystem

The EHDS stakeholder ecosystem should be funded through a **light, enabling and diversified model** that ensures continuity and credibility without creating dependency, capture, or undue influence. Funding arrangements should reflect the ecosystem's complementary role, its public-interest purpose, and the voluntary nature of stakeholder participation. The long-term sustainability of the ecosystem should depend on its demonstrated usefulness to EHDS implementation, particularly its ability to provide timely, actionable input and reduce implementation risk rather than on guaranteed or permanent funding. Periodic review of relevance, outputs and operating costs should be built into the model.

While funding a lightweight stakeholder ecosystem orchestrator is a small part of the EHDS2 compliance investment needed to ensure availability of high-quality standardised datasets, this small investment and commitment can significantly improve coordination, risk identification and stakeholder alignment.

Funding arrangements should be designed to prevent undue influence by any single actor, whether public or private. No contributor should be able to steer priorities, outcomes, or

conclusions through financial leverage. Transparency about funding sources and uses is therefore essential to maintaining trust and legitimacy.

Core public funding for coordination and enablement

Public authorities should provide targeted and limited funding to support the basic functioning of the ecosystem. This funding should be restricted to:

- √ a small coordination and facilitation office,
- √ organisational support for meetings and workstreams,
- √ documentation, synthesis, and publication of outputs, and
- √ transparent operation and communication.

This core funding ensures stability, continuity and legitimacy. It should be treated as an **enabling investment**, not as programme funding. Core public funding should consider enabling patient and citizen organisations to parcipate meaningfully, covering time, capacity-guilding and facilitation support without creating conflicts of interest.

Predominant reliance on in-kind stakeholder contributions

The substantive work of the ecosystem should be driven primarily by **in-kind contributions** from participating stakeholders, including time, expertise, data, pilot environments, and methodological input. This approach reinforces shared ownership of outcomes, ensures relevance to real-world practice, limits financial barriers to participation, and discourages passive or symbolic engagement. Participation should remain voluntary and proportional, with expectations adapted to stakeholder capacity and should not confer any preferential rights regarding access to health data under EHDS2, which remains governed exclusively by the Regulation and National Implementing Authorities.

Targeted use of project and programme funding

Where appropriate, time-limited external funding (including EU programmes, national funds, or research and innovation instruments) may be used to support specific pilots, methodological development, or cross-border alignment activities. Such funding should be clearly scoped and time-bound, complement (not replace) core coordination funding and avoid locking the ecosystem into project-driven logic.

6. Conclusions

The European Health Data Space offers Greece a transformative opportunity to modernise healthcare, enhance patient trust, and unlock the full potential of health data for care, research, and policy-making. Achieving this requires moving beyond formal regulatory compliance to create an environment in which data are reliable, interoperable, and meaningful for both primary and secondary use.

A structured stakeholder ecosystem is central to this ambition. By complementing institutional governance with coordinated, purpose-driven engagement, Greece can achieve shared learning, practical problem-solving, and voluntary alignment across the diverse actors, reduce implementation risks, strengthen trust, and ensures that the benefits of EHDS are tangible for patients, citizens, professionals and innovators alike.

Immediate next steps include launching the coordination function, initiating targeted workstreams and establishing structured feedback loops with institutional authorities to ensure alignment, relevance and measurable impact.

Embedding a complementary stakeholder ecosystem within Greece's EHDS implementation will both ensure compliance and maximise the value of health data, enhance system resilience and position Greece as a regional leader in digital health innovation.

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Disclaimer

This document reflects the synthesis of stakeholder discussions and expert analysis. It does not represent the official position of any public authority or participating organisation.

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