Workshop on collaboration on data discovery and multi-country applications under EHDS

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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PariSanté Campus

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About the workshop

The workshop aimed to address the challenges and potential solutions for improving collaboration between Health Data Access Bodies (HDABs), data users, and data holders. The discussions focused particularly on cooperation during the data discovery phase and within the context of multi-country applications. A total of 150 participants joined the event- 50 in person and 100 online. The workshop also featured expert presentations, providing valuable insights and framing the discussions around practical experiences and use cases. Throughout the sessions, participants explored current practices, identified what works well, and discussed gaps and opportunities for improvement, especially in light of the upcoming European Health Data Space (EHDS). Key questions included what will change with the EHDS, and what infrastructures or workflows may need to evolve to meet its requirements. Key themes discussed were the challenges and possible solutions to strengthen collaboration between HDABs, data holders and data users, particularly regarding multi-country applications and the data discovery phase. The discussion was also focused in examples and models for cooperation across stakeholders to guide future work towards the implementation of the secondary use framework of EHDS Regulation.

Presentations

1. Introduction by TEHDAS2 WP4 co-leads Alexander Leander Knudsen, Anne Sofie Skødt Jørgensen and Louisa Stüwe

This workshop marks the second of three workshops under TEHDAS2 Work Package 4, which focuses on developing collaboration models for the EHDS. The workshop series is structured around three main topics: Ethics (the first workshop, held in June 2025), Collaboration (the current workshop), and intellectual property rights and trade secrets (planned for March 2026). Collectively, these workshops aim to engage stakeholders, ensure transparency, and develop actionable policy recommendations that support the effective implementation of the EHDS.

2. Setting the Scene: Prof. Antoine Tesniére, Director at PariSanté Campus

Antoine Tesniére highlighted PariSanté Campus as a prime example of the kind of cross-sector collaboration model that the EHDS seeks to promote, bringing together researchers, clinicians, startups, and national institutions to drive data-driven health innovation. He emphasized that secure and ethical access to health data is essential for advancing digital health, artificial intelligence, and innovation across Europe. According to Antoine, the EHDS is more than just infrastructure; it represents a societal transformation that enables cross-border data flows, public trust and strong governance, and the responsible reuse of health data. In his own words “[the EHDS] represents a new way of thinking - one in which health data is no longer a passive by-product of care, but an active resource for research, innovation, and public policy”. Further: “Secondary use of health data can become one of the most powerful drivers of progress in the coming decade. It allows us to accelerate medical discoveries, improve health system performance, and support evidence-based decision-making. But achieving this potential requires more than technology: it demands cooperation, alignment, and above all, trust”. He pointed to real-world successes that already demonstrate the value of secondary data use, at national, European and global level. For example, he mentioned France’s Health Data Hub which has enabled large-scale AI projects in cardiology and rare diseases, strengthening both public research and private innovation, as well as EU-wide COVID-19 data sharing, which enabled faster insights and responses. Over the next three to five years, the expected benefits of the EHDS include better benchmarking and quality improvement in hospitals, faster research approvals, stronger public health surveillance, high-quality data access for AI and digital health industries, and greater transparency and empowerment for citizens. Antoine underlined that education, dialogue, and demonstration are critical to building public trust, and noted that the ongoing work in TEHDAS2 on cooperation, ethics, and ownership will directly shape the upcoming implementing acts and lay the operational foundation of the EHDS. He concluded by stressing that the EU now has a unique opportunity to become a global leader in trusted and innovative health data sharing, truly “turning shared data into shared value”.

3. Perspectives of the European Commission: Mélodie Bernaux, DG SANTÉ

It was emphasised by Mélodie Bernaux that practical collaboration among Health Data Access Bodies (HDABs), data holders, and data users is essential to make the EHDS work in practice, beyond legal and technical frameworks. She explained that TEHDAS2 aims to operationalise the EHDS regulation through guidelines and technical specifications, with Work Package 4 focusing on collaboration models, ethics, intellectual property rights, and cross-country cooperation. Key challenges include supporting data holders in meeting obligations, enabling data users to understand and use datasets effectively, ensuring coordination and trust between HDABs and trusted data holders, and structure processes across countries. Melodie stressed that collaboration prevents fragmentation, builds trust, and ensures predictability for all actors. To achieve this, she called for practical tools, guidance, and best practices, concluding that collaboration and stakeholder input are vital to turning the EHDS into a functional and trusted system.

4. National perspective: Emilie Passemard, Digital Health Delegation, French Ministry of Health

In the French presentation from Emilie Passemard, the speaker outlined France's approach to preparing for the implementation of the EHDS regulation, emphasizing consultation, collaboration, and trust as essential elements. France is actively aligning with upcoming EU regulations while anticipating the necessary national adaptations. Several key actors from the French health data ecosystem: the Digital Health Delegation, responsible for preparing EHDS implementation and adapting national law; the National Digital Health Agency, which ensures deployment and compliance with digital health standards; the National Health Insurance Fund, which defines national insurance policy; the French Health Data Hub, which may serve as the HDAB for secondary data use; and the National Health Innovation Agency, focused on furthering digital health innovation. France is prioritizing early preparation, participating actively in EU negotiations, and launching a national strategy for the secondary use of EHR data and AI. A broad consultation process has involved public institutions as well as patients, caregiver associations, industry representatives, and researchers, using webinars, online and in-person meetings, and written contributions. This early and inclusive engagement is seen as key to successful regulation. Public outreach is supported by tools such as a dedicated webpage and a LinkedIn video series with monthly episodes. The national strategy on secondary use and AI is nationally oriented but aligned with the EHDS, taking into account data protection authority roles, fee structures, opt-out processes, and issues of data sovereignty and localization. The presenters noted ongoing challenges, including political instability affecting legislative work and the need for strong coordination among many institutions and stakeholders.

5. National Perspective: Jacob Hartmann Sørensen, Danish Health Data Authority

In the presentation from DHDA, Jacob Hartmann Sørensen outlined Denmark's strong position in health data, built on rich, high-quality, population-wide datasets linked through the national social security number, a high level of digitalisation, and an active life-science sector. Despite

these strengths, several challenges were highlighted: the data landscape remains fragmented, researchers must navigate multiple authorities and differing application processes, existing secure processing environments are restrictive, and it is difficult to combine datasets with modern analytical tools. To address these issues, Denmark has launched a national strategy under the government's life-science agenda and recent health reforms, aiming to make better use of health data for researchers, companies, authorities, clinicians, and citizens. Two major national solutions are in development: a single point of contact (national HDAB) that will allow users to request access to multiple datasets through one portal, and a national analysis platform that will enable approved secure analytical environments to work with data, without creating a single monopoly system. A user-friendly metadata catalogue is central to this effort, designed to be searchable and to document datasets down to the variable level to simplify data discovery. Work is ongoing to define governance, security requirements, and technical standards so the national solutions align with the evolving EHDS framework. In response to questions, Jacob noted that many publicly funded registries could potentially receive an EHDS quality label, though significant work remains to clarify requirements and prepare the datasets accordingly.

Session 1 – Data Discovery

Session 1 on data discovery explored the challenges and possible solutions in the first step of the data application process.

Presentation: Marije van Melle, Nictiz, Netherlands
Marije van Melle presented the data holder perspective within the EHDS, highlighting the diversity of organisations involved and the challenge of establishing consistent processes across Member States. She outlined the necessary interactions between data holders, HDABs, data users and SPEs throughout the entire data access pathway, stressing that early engagement during discovery and request phases can support clearer and more feasible data requests. A central point was the need for structured communication channels and traceable workflows to avoid issues in data provision and use. Marije also noted that many responsibilities and operational arrangements still need to be defined nationally, requiring Member States to balance roles between HDABs and data holders to ensure capacity and compliance with data quality and security requirements. She concluded by recommending that Member States invest in communication infrastructures, formalised clarification procedures and appeal mechanisms, emphasising that early, continuous dialogue is essential to prevent challenges later in data preparation and provision.

Presentation: Pekka Kahri, Helsinki University Hospital, Finland
Pekka Kahri shared experiences from Helsinki University Hospital and the phems project (link), highlighting practical approaches to multi-country data collaboration in pediatrics. He discussed how federated analytics and harmonised data models allow hospitals to collaborate without transferring sensitive patient-level data, while enabling cross-border research and benchmarking. The presentation emphasised key challenges in multi-country applications, including data discovery, study feasibility, cohort definition, and statistical power, particularly in small or rare patient populations. Pekka highlighted the importance of aligning national practices with the emerging EHDS framework, ensuring that technical standards, metadata, and permit processes are compatible. A central message was the need for structured governance, scalable collaboration networks, and clear operational processes to support efficient and trustworthy multi-country research, creating a feedback loop that benefits both data holders and users while preparing hospitals for future EHDS requirements.

Presentation: Clément Henin, AP-HP, France
Clément Henin presented the approach to data discovery at the AP-HP Clinical Data Warehouse, highlighting the scale and complexity of managing data from 38 hospitals covering around 8 million patients annually. He shared AP-HP's experience in providing data for secondary use, outlining the current processes for enabling research while ensuring data quality, security, and compliance. The presentation highlighted key challenges, including retro-engineering legacy systems, heterogeneous devices, and variability in data quality across hospitals. Clément showcased tools developed to support data discovery, such as Cohort 360 for cohort building, expert feasibility meetings for complex projects, and emerging solutions like data lineage tracking and the Panorama EDS portal. Lessons learned from these practices emphasize the importance of robust data quality checks, structured workflows, and interoperability standards like FHIR. He also highlighted that although HL7/FHIR is used, different versions of HL7 is as well a challenge from an interoperability point of view when creating a shared platform for collaborations around patient data. A key message was that these experiences provide practical insights for establishing frameworks under the EHDS, demonstrating the need for scalable, efficient, and transparent processes to support researchers and data users across large, complex health data environments.

Plenary Discussion on Health Data Discovery moderated by Michael Peolsson, The Swedish eHealth Agency

The plenary discussion focused on practical experiences in collaborative models for data discovery, exploring what works today, existing gaps and challenges, and lessons for implementing the framework for secondary use under the EHDS Regulation.

Key discussion points:

- **Early and structured engagement:** All speakers emphasized the critical role of early interactions between data holders and data users. Structured communication channels, expert meetings, and iterative discussions during the data discovery phase prevent misunderstandings, improve data quality, and ensure compliance before data use.
- **Inclusive approach to data holders:** Attention must be given to both large, mature institutions and smaller or less-resourced data holders. Supporting smaller organizations with guidance, tools, and standard processes is essential to create an inclusive EHDS ecosystem.
- **Data quality and interoperability:** High-quality, well-understood data is fundamental. Data quality checks, engagement with clinical experts, standardized coding systems (e.g., FHIR, SNOMED), and automated pipelines were highlighted as critical enablers. Semantic harmonization and the one-time coding principle reduce redundancy and support multiple uses.
- **Collaboration models and governance:** Experiences in pediatrics, cancer, and other thematic networks demonstrate the value of thematic collaboration groups and expert committees. Expanding perspectives to include patients, citizens, and private-sector actors to enhance trust, ensure ethical oversight, and support public interest. It was argued not forgetting already established infrastructures for health data discovery and sharing, e.g. research and industrial infrastructures.

- **Operational challenges:** Key barriers include the speed of processes, administrative and technical delays, cost of infrastructure (e.g., SPE), and scalability across multiple countries. Transparent cost estimation and traceable workflows were suggested as ways to mitigate these challenges.
- **Future EHDS implementation:** Infrastructure, IT processes, and governance frameworks must be designed to facilitate transparent, traceable, and scalable interactions. Demonstrating the added value of EHDS, improved science, patient outcomes, and healthcare efficiency, is crucial to sustain engagement over the long term.

Key takeaways:

- Early, structured collaboration and communication prevent issues and enhance compliance.
- Data quality, standardization, and interoperability are essential for secondary use at scale.
- Inclusive, multi-stakeholder governance models build trust and ensure ethical use.
- Addressing operational challenges (cost, speed, scalability) is key for an effective EHDS.
- Demonstrating tangible value to patients, healthcare systems, and researchers is critical for sustaining investment and engagement.

Session 2 - Multi-country Collaboration

Session 2 on multi-country collaboration explored the challenges and possible solutions when multiple HDABs from different countries oversee the same application.

Presentation: Jasmin Schulz, Luxembourg Institute of Health

Jasmin Schulz presented the Clinnova initiative, a cross-border precision medicine project uniting partners in Luxembourg, Germany, France, and Switzerland to build an interoperable, patient-centric data environment with high-quality, standardised data. She outlined Clinnova's goals to establish shared data infrastructures and workflows, connect local Data Integration Centres in a federated network, and enable remote data analysis through federated learning, with current proof-of-concepts in inflammatory bowel disease, rheumatic diseases, and multiple sclerosis. Jasmin described interaction processes between data holders and users, including local access committees and a federated data catalogue that increases dataset visibility and supports transparent multi-country requests. The presentation also highlighted opportunities the EHDS can bring, such as streamlined cross-border access, greater transparency, and improved visibility for collaboration, alongside challenges like administrative burdens, risks of HDAB incompatibility, multiple parallel applications, and questions of governance and fair compensation. The presentation concluded with lessons from Clinnova's federated, patient-focused model, stressing clinician engagement, harmonised standards, and scalable processes to support cross-border research and inform EHDS implementation.

Presentation: Amélie Schäfer, Health Data Hub, France
Amélie Schäfer presented the French Health Data Hub's current collaboration models, as a perspective of a future HDAB, outlining its role as a national "one-stop shop" for accessing health data in projects serving the public interest. She described HDH's collaboration models with data holders, data users, citizen-patients, and decision-makers, emphasizing support throughout the project lifecycle, including guidance on dataset identification, matching strategies, agreement drafting, and technical platform use. HDH also manages ethical and scientific review in coordination with the Data Protection Authority and works to streamline procedures at the national level. Amélie highlighted HDH's initiatives to foster innovation and standardization, such as national calls for projects, the development of a national data catalogue linked to the SNDS and hospital data warehouses, and the creation of strategic reference databases. At the European level, HDH participates in projects like TEHDAS2, Quantum, and SHAIPED, integrating French data holders and leveraging federated approaches for AI and medical device development, while also supporting international collaborations through anonymized data and federated testing. Key messages included the importance of transparent governance, robust citizen engagement, data standardization, sustainable financing, and scalable processes to enable both national and cross-border health data access, providing practical insights for EHDS implementation.

Presentation: Inge Franki, Health Data Agency, Belgium
Inge Franki presented challenges and concerns from the perspective of the Health Data Agency – the future Belgian HDAB, focusing on operational insights from handling data access applications and multi-country requests. Inge explained that the HDA is preparing to act as the Health Data Access Body (HDAB) by 2029, while already facilitating requests, onboarding data holders, and developing a metadata catalogue. Inge highlighted challenges in multi-country research, including limited catalogue coverage, heterogeneous data sources and registries, harmonization of categories for minimization, and uncertainty around decision-making for international Secure Processing Environments (SPEs). Practical issues include tracking multi-country requests, avoiding duplicate patient records, and handling invoicing across multiple HDABs. She shared lessons from use cases, such as measles, which revealed difficulties in discovering and combining data across countries and underscored the need for clear governance, automated support, standardized metadata, and coordinated processes for risk analyses like small-cell calculations. These experiences provide valuable operational insights for implementing EHDS-compliant processes and preparing HDABs to efficiently manage cross-border research while ensuring legal, ethical, and technical compliance.

Breakout Sessions

In the breakout sessions in-person participants chose one of three topics to discuss, forming three smaller discussion groups. Online participants had the opportunity to answer the questions of all topics in text. Following the breakout sessions key takeaways from each group were presented by the moderator of the group. The summaries below consist of key takeaways from the plenary session, representing the on-site participants discussions, as well as key points from the written answers by the online participants.

Group 1: Governance and Coordination among HDABs

Moderated by Louisa Stuwe, Digital Health Delegation, French Ministry of Health

- Group 1 examined governance models and coordination mechanisms to support consistent and efficient collaboration between HDABs when handling multi-country data applications. The group explored how responsibilities should be shared between national and EU-level actors, what structures could ensure transparency and trust, and which operational tools are needed to manage cross-border processes effectively.

Key takeaways:

- Improve transparency and coordination for multi-country requests: Ensure systematic notification of involved countries and develop automated tools or shared templates to exchange request information and outcomes.
- Clarify governance roles across national and EU levels: Define responsibilities for HDABs, HealthData@EU structures, and data holders, including how coordination of Secure Processing Environments and parallel requests should be managed.
- Strengthen national and cross-border structures for collaboration: Establish national committees or coordination points, supported by shared dashboards and monitoring tools to track fees, delays, acceptances, and compliance.
- Develop common guidelines and mutual agreements: Use EHDS-level guidance to support trust, communication, and consistent collaboration between HDABs, including mechanisms for handling opt-outs and accountability across jurisdictions.
- Address operational challenges proactively: Improve workload management, request tracking, and efficiency tools to ensure practical, scalable governance for multi-country applications.

Group 2: Mutual recognition mechanisms across borders

Moderated by Beatriz Barros, Sciensano

- The group focused on potential mutual recognition mechanisms that could reduce duplication of effort in evaluating multi-country applications. The discussion centered around the idea of a “main HDAB” responsible for the centralized evaluation of harmonized aspects of a multi-country application. These harmonized topics could include legally defined purposes, certain ethical standards, or other areas where evaluation can be standardized across countries. National HDABs would then retain responsibility for country-specific evaluations, such as methodological considerations, cohort definitions, or locally relevant ethical aspects. Trust and transparency were identified as key prerequisites for mutual recognition to function effectively. Participants highlighted the importance of European-level guidelines to standardize evaluation procedures and to ensure consistent handling of IP rights, trade secrets, and other sensitive information. While the main HDAB approach could reduce duplicated effort, the risk of bottlenecks and workload concentration was acknowledged. Examples from mutual recognition frameworks in clinical trials by EMA were suggested as potential lessons to inform this model.

Key takeaways:

- Implement a tiered evaluation model: central evaluation for harmonized topics + national evaluation for country-specific aspects
- Develop clear European-level guidelines for mutual recognition and harmonized evaluation
- Build trust and transparency between HDABs to support shared responsibility
- Balance responsibilities to avoid bottlenecks in centralized evaluation
- Consider lessons from other mutual recognition frameworks (e.g., clinical trials) to inform practice
- Harmonize evaluation of sensitive topics like IP rights and trade secrets to reduce duplication

Group 3: Operational Implementation and future outlook

Moderated by
Michael Peolsson, Swedish e-Health Agency

- Group 3 focused on the operational conditions required to support smooth multi-country processes under the EHDS, including tools, resources, governance structures, and interactions between HDABs, data holders, and data users. Drawing on policy, governmental, academic, and industry perspectives, the discussion centered on how to create efficient and user-friendly workflows that can operate across Member States with diverse levels of preparedness.

Key takeaways:

- Create a unified and efficient application process: Establish a single entry point, harmonized application materials, and streamlined procedures to reduce redundancy and avoid parallel assessments.
- Balance standardization with national flexibility: Standardize essential protocols and templates while allowing adaptation to different maturity levels and country-specific requirements.
- Strengthen coordination structures and governance models: Set up national contact points, clarify roles between national and cross-border actors, and define agreements and responsibilities for both public and private data holders.
- Adopt user-centric and security-focused design: Map user journeys across applicant types and ensure workflows support secure, compliant data sharing with consistent metadata and robust protection standards.
- Use practical use cases to guide implementation: Develop concrete examples to translate EHDS requirements into workable processes for HDABs, data holders, and data users.

Closing remarks by Elina Drakvik, Sitra, TEHDAS2 Coordinator

In her concluding remarks, Elina Drakvik emphasised the importance of aligning national efforts as the EHDS evolves from legislation to practical cooperation. She highlighted the value of stakeholder engagement, concrete national examples, and the need for clear processes between HDABs, data holders, and data users. A major theme was the importance of investing in data quality, developing shared approaches to assessing long-term impact, and strengthening trust through transparent communication. She also underscored the need for more practical experience through real-life use cases and pilots to ensure that guidelines and processes are feasible and well-tested.

"To ask the right questions and to be truly prepared, we need to practise through pilots and more use cases and, importantly, we must continue working together so we all move in the same direction"

Future outlook

- Workshop 3 on IP rights and trade secrets to be held in March in Brussels