Summary report

Workshop on gaps and future needs for successful implementation of the secondary use framework under the EHDS

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The invited speakers from Member States shared experiences and reflections that do not necessarily comprise an official Member State point of view, nor decided policies.

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Executive summary

This document describes the main outcomes and results of a workshop aimed to identify the key implementation needs emerging from ongoing European projects and Member States to support the implementation of the European Health Data Space (EHDS), with a focus on the secondary use of health data. By bringing together representatives from European projects, the European Commission and Member States, the workshop provided a platform to exchange experiences, identify common challenges and discuss practical solutions to facilitate the operational implementation of the EHDS.

Participants identified a number of priority areas requiring further operational level guidance and coordinated efforts. These include piloting multi-country applications, strengthening Secure Processing Environments (SPEs), improving data harmonisation and semantic interoperability, and developing additional business capabilities required under the EHDS. Enhancing scalability, translating the results of European projects as well as strengthening stakeholder engagement across the EHDS ecosystem were considered important aspects to be taken into account.

Furthermore, the workshop participants highlighted the importance of developing shared SPEs and advancing federated analysis capabilities to support secure cross-border use of health data., Developing common reference architectures for SPEs and establishing harmonised privacy and security practices would be valuable to support the consistent evolution of SPEs in Member States.

AI readiness tools that support data holders in achieving compliance with the European Health Data Space (EHDS) are identified as a crucial enabler of successful implementation, while also recognising that effective deployment depends on robust governance, appropriate technical infrastructure, data quality and clear operational guidance. Investments in "AI-ready" SPEs, together with harmonised approaches to regulation and data governance, will be essential for enabling responsible use of AI within the EHDS.

At the same time, data holders will need clear operational support, onboarding, tools and guidance to fulfil their obligations under the EHDS framework. Incentives may be useful to support early readiness, improve data quality and metadata completeness, and encourage the sharing of implementation experience, but should not be framed as a condition for compliance. Clear communication and comprehensive onboarding activities at national and regional level will be important to reduce friction and support effective implementation as data permit processes evolve under the EHDS framework.

Further development of operational models that enhance transparency for citizens, including work on practical approaches for implementing opt-out mechanisms and actively communicating how health data are used to generate public value as well as increasing readiness for demonstrating the impact of EHDS are also important future steps. Strengthening the operational capacity of HDABs and sharing of good practices continue to be crucial for the next phases of implementation. Carrying out multi-country pilot projects, more operational implementation guidance, common templates and practical repositories of use cases and challenges are important next steps for gaining hands-on experience, enabling testing of solutions, and accumulating the learnings in order to promote consistency as the implementation progresses.

In conclusion, sustained national commitment, complemented by coordinated European funding instruments will be essential to support implementation and capacity building. Investments in training, more operational guidance and scalable tools will be needed to support both mature and less mature Member States, including data holders in fulfilling their EHDS obligations. Incentives may be considered to support early readiness, data quality improvement and the sharing of good practices, while the value of EHDS should also be clearly demonstrated to the broader ecosystem and citizens.

About the workshop

The workshop was held 29 May 2026 in Brussels and online, organised by the EHDS2 Community of Practice and TEHDAS2 joint action. The workshop brought together around 130 participants altogether, onsite and online. The workshop aimed to identify the key implementation needs emerging from ongoing European projects and Member States to support the implementation of the European Health Data Space (EHDS), with a focus on the secondary use of health data. By bringing together representatives from European projects, the European Commission and Member States, the workshop provided a platform to exchange experiences, identify common challenges and discuss practical solutions to facilitate the operational implementation of the EHDS.

The workshop built on discussions initiated during the General Assembly of the Community of Practice in March 2026, where participants identified a number of priority areas requiring further guidance and coordinated action. These included enabling multi-country applications, strengthening Secure Processing Environments (SPEs), improving data harmonisation and semantic interoperability, and developing additional business capabilities required under the EHDS, enhancing scalability, and translating the results of European projects as well as strengthening stakeholder engagement across the EHDS ecosystem.

Building on these identified priorities, the workshop explored how ongoing key initiatives, including TEHDAS2, VALO, SHAIPED, and QUANTUM and the needs and gaps identified from the projects' and Member States' perspective can support identification of the remaining implementation challenges and what are the concrete suggestions for future measures in order to bridge the gaps.

The discussion of the TEHDAS2, EU-HIP and QUANTUM project were followed by an action definition exercise, in which all participants were asked to identify and suggest possible actions to take via Wooclap. The results of that exercise are summarized in the Annex.

Introduction

Speaker: *Fulvia Raffaelli, DG SANTE, European Commission*

Fulvia Rafaelli emphasised that the EHDS creates legal obligations, but that successful implementation also requires cooperation to turn these obligations into operational systems and concrete benefits for European citizens, healthcare, research and innovation.

The importance of clarity in the implementation of the secondary use of electronic health data was also highlighted. Stakeholders are unlikely to engage effectively with processes that are perceived as unclear or overly complex. Therefore, it is necessary to first focus on establishing the basic requirements to ensure that EHDS is operational, while additional features can then be worked on at a later stage.

The importance of continuity was also stressed. The knowledge, guidance and practical experience generated through projects should not remain confined to project reports but should inform governance and implementation. A realistic approach to implementation is important. Where challenges or limitations are identified, these should be communicated openly, and concrete solutions are needed to bridge the remaining gaps.

Session 1. Needs identification: TEHDAS2 and VALO projects

Moderator: *Beatriz Barros (Sciensano)*

Gaps and needs identified by TEHDAS2 and VALO

Presenters*: Elina Drakvik, TEHDAS2, and Mikael Rinnetmäki, VALO (Sitra, Finland)*

Elina Drakvik presented the progress of the TEHDAS2 Joint Action, which has developed a comprehensive set of guidelines and technical specifications to support the implementation of the European Health Data Space (EHDS) for the secondary use of health data. While several of the outputs support the European Commission in the preparation of the EHDS Implementing Acts, others provide guidance to health data holders and health data users and especially for Health Data Access Bodies (HDABs) to guide in the various organisational, technical and governance aspects of implementation.

Mikael Rinnetmäki introduced the VALO (Value from Nordic Health Data), a Nordic collaboration project that aims to establish common principles for implementing the EHDS Regulation across the Nordic countries. The project facilitates cross-border research, innovation and policy development by promoting interoperable approaches, testing cross-border data use through pilot projects and strengthening collaboration between national authorities.

The presentations highlighted several implementation challenges. Although significant progress has been made in developing guidance and technical specifications in TEHDAS2, further work on their "tooling" and enhancing operational level details are required to ensure that they can be implemented consistently across Member States. Key priorities include enabling efficient multi-country applications and establishing repository of challenging cases/learnings, strengthening the capacity and scalability of work of HDABs (incl. fees, international access and enforcement issues), advancements in sharing Secure Processing Environments (SPEs), and improving stakeholder engagement and governance e.g. through establishment of communities of practice of data holders and users and by developing feedback loops to gather stakeholder input for continuous feedback and learning to refine the guidance based on practical experience. Also, further measures on citizen rights and participation were highlighted as well as developing evaluation measures for demonstrating the impact of EHDS for enhancing transparency and trust.

Experiences collected from the VALO project indicate that incentives should be considered especially for data holders to provide both data and metadata descriptions in best possible format. These incentives should be long term ones, not temporary grants. Incentives should also be considered for early implementation of EHDS requirements, and for sharing results and implementation details. These incentives can be short term ones. Any discussion on incentives should be understood as supporting early readiness, data quality, metadata completeness and sharing of implementation practices, without prejudice to the legal obligations of data holders under the EHDS.

Experiences from the VALO project further highlight the vulnerability of the opt-out model. Even a rumour or a suspicion of potential misuse or of a controversial party accessing health data may trigger large populations to use their opt-out right. Therefore, the opt-out mechanism should be as fine-grained as possible, to allow targeting any boycotts to specific actors without affecting others. Also, an opt-in mechanism based on consent could be considered as a parallel mechanism to the opt-out model. Experiences from the VALO project underlined the importance of public trust, clear communication and transparency in the implementation of secondary use of health data. Participants noted that opt-out mechanisms under the EHDS will need to be implemented in a clear, accessible and legally sound manner, accompanied by communication on safeguards, permitted purposes, prohibited uses, governance and the public value generated by health data reuse. Further operational guidance and

exchange of experience may help Member States implement these mechanisms consistently and maintain trust.

Reflections from Member States

Speakers: *Mervi Siltanen (Findata), Bert Verdonck (Luxemburg National Data Service or LNDS), and Katharina Schneider (Data Access and Coordination Office, Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM)*

The speakers underlined that EHDS implementation requires adequate national and European funding. Limited financial resources, shortages of technical expertise and varying levels of organisational maturity continue to present challenges in many countries. Investments are needed to strengthen technical infrastructure and to catalyse the work on data catalogues, while also addressing workforce capacity questions that many HDABs are facing.

Regardless of organisational structures, clear governance arrangements and close collaboration between national authorities will be essential for successful implementation. Formal establishment of European and national stakeholder groups, including networks of coordinating HDABs and thematic communities addressing issues such as sanctions, data governance and operational implementation, was suggested as a concrete measure. Furthermore, expanding existing national collaboration between data holders, researchers and competent authorities was considered important for building practical experience. Enabling good collaboration between Member States was considered essential to promote harmonised approaches while respecting national differences.

Importance of developing federated analysis capabilities, increasing access to high-performance computing resources to support large-scale research and EU-level recommendations on handling large-scale data (volume, transfer, processing) were highlighted as important aspects. It was also noted that the practical operation of cross-border SPE usage remains insufficiently defined. Questions concerning secure data transfer, interoperability between national SPEs and governance arrangements require further clarifications to enable efficient multi-country research while maintaining high standards of data protection. Concrete cross-border pilot projects were highlighted as a specific measure to tackle many of these questions.

Conclusion

Continued cooperation between Member States, the European Commission and key European projects will be essential to translate existing guidance into harmonised operational practice and tools. Addressing these needs requires greater clarity across some of the legal, technical and practical dimensions of EHDS, as well as the development of concrete cross-border use-cases and appropriate incentives to advance the practical level implementation.

Session 2. Needs identification: SHAIPED project

Moderator: *Katharina Schneider (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM)*

Gaps and needs identified by the SHAIPED project

Presenter*: Pauline Cohen (French Health Data Hub)*

Pauline Cohen presented the SHAIPED project, which supports Health Data Access Bodies (HDABs) in establishing pathways for the development, evaluation and deployment of Artificial Intelligence (AI)-based medical devices within the EHDS framework. The project aims to facilitate the safe and effective use of health data for AI development while ensuring compliance with the regulatory, technical, and ethical requirements.

The presentation highlighted that the readiness of Secure Processing Environments (SPEs) remains one of the key prerequisites for enabling AI development. Future SPEs should incorporate functionalities that support the complete AI development lifecycle, including data linkage, annotation, and model development. The project also identified the need to establish harmonised procedures for secure and controlled export of AI models and analytical outputs from SPE's, subject to appropriate disclosure control, risk assessment and safeguards, as existing operational practices remain underdeveloped. In addition, data harmonisation, interoperability, and consistent technical standards were recognised as essential enablers for cross-border AI development and validation.

Reflections from Member States and from the AIDAVA project

Speakers: *Justin Ansotte (Belgian Health Data Agency or HDA) and Christina Hilmarsen (Norwegian Institute of Public Health), Isabelle de Zegher (AIDAVA)*

The Member State contributions highlighted the operational challenges that Health Data Access Bodies are likely to encounter as AI applications become more prevalent within the EHDS. A common theme was the need for greater flexibility in the management of AI research projects. Belgium highlighted the practical difficulties of estimating computing resources and infrastructure requirements at the application stage, making it also challenging to establish predictable fee structures. As AI projects frequently evolve during development, participants also emphasised that data access permits and Secure Processing Environments should be sufficiently flexible to accommodate justified changes in research needs without creating unnecessary administrative burden.

The discussions further demonstrated the complexity of applying existing data governance principles to AI development. Modern AI models often require access to large and diverse datasets, creating practical challenges for the implementation of the data minimisation principle. Hence, HDABs face a difficult task of assessing whether requested datasets are proportionate for the given purpose, while recognising that applicants possess the detailed knowledge of their analytical methods. This underlined the importance of clear application processes, transparent justifications from applicants and operational level guidance to support consistent decision-making.
Also, the discussions warned for careful consideration of possible person-identifiable data resulting from AI models in the SPE and that this should be anticipated (warning, expert considerations).

Furthermore, it was recognised that implementing AI within the EHDS requires careful alignment between the EHDS Regulation, the General Data Protection Regulation (GDPR) and the evolving regulatory framework for AI. Ensuring that these frameworks can be applied coherently will be essential for enabling innovation while maintaining a high level of data protection and public trust.

The complementary role of the AIDAVA project was also presented. The project illustrates how AI can support researchers and data users in navigating increasingly complex analytical workflows, while reducing technical barriers and promoting access to advanced analytical capabilities.

Conclusions

Harmonised approaches to data governance, interoperability and regulatory interpretation are essential to ensure that AI can be developed responsibly across Member States. Leveraging AI within the EHDS

requires both development of operational guidance and investments in infrastructure, enabling AI tools in secure processing environments. The SPEs should provide integrated environments that support various AI development and validation efforts, maximising the benefits for research and innovation while also aiming to reduce the risk of widening disparities in digital maturity across Europe.

Session 3: Needs identification: EHDS and EU-HIP

Moderator: *Dana Eleftheriadou (DG SANTE, European Commission)*

Gaps and needs identified from EU-HIP

Presenter: *Cátia Pinto (SPMS, Portuguese Ministry of Health)*

Cátia Pinto presented the EU-HIP (Health Intelligence Platform) project, which supports Member States in strengthening national health information systems and preparing for interoperability with the future HERA IT platform. The project contributes to the broader objectives of the European Health Union by facilitating coordinated health intelligence, public health surveillance and preparedness for cross-border health threats.

The effectiveness of the future HERA IT platform will depend on the availability of robust, interoperable national health information systems. Consequently, EU-HIP supports participating countries in developing new digital infrastructures while strengthening and aligning existing national systems to enable the efficient exchange of information related to health threats, epidemic intelligence and medical countermeasures.

A key objective of the project is to improve interoperability and data comparability across Member States by promoting common approaches to data collection, reporting and system integration. In addition, EU-HIP will facilitate integration of national IT systems with the HERA IT platform currently under development, and complement existing systems for early warning and response, epidemic intelligence, public health surveillance and medical countermeasures.

Several questions remain opened regarding the link between the HERA IT platform and the EHDS2 infrastructures, which urgently need to be clarified to avoid duplication of efforts.

Reflections from Member States

Speaker: *Fidelia Cascini (National Institute of Health, Italy)*

Coordinated governance and collaboration between Member States will ensure that health information can be exchanged efficiently during both routine public health activities and cross-border emergencies. Strengthening national digital capabilities today will be essential not only for future preparedness but it can also support the wider implementation of the EHDS, enabling secure, high-quality data exchange across Europe. Potential synergies between public health surveillance systems, the future HERA IT platform and EHDS/HealthData@EU should be further clarified to avoid duplication and ensure coherent governance, legal basis and technical interoperability.

Conclusions

The national health information systems are a fundamental prerequisite for the implementation of HERA IT platform. Investments in digital infrastructure, common standards and coordinated

governance will be required to improve data comparability, streamline reporting processes and strengthen Europe's capacity to respond effectively to future public health threats.

Session 4. Needs identification: QUANTUM project

Gaps and needs identified by the QUANTUM project

Presenter: *Enrique Bernal Delgado (IACS, Spain)*

Enrique Bernal Delgado presented the QUANTUM project, which has established a common European framework for assessing and describing the data quality and utility of health datasets for secondary use. The project has developed a data quality and utility label that provides transparent information on the quality of datasets and maturity of data holders, enabling researchers and data users to better understand the characteristics and suitability of available data for their research purpose. To ensure broad applicability across different research and innovation contexts, and to accommodate the highly heterogeneous nature of health data across the EU, the QUANTUM framework uses an agnostic approach.

The presentation highlighted several priorities for the further deployment of the QUANTUM framework. In the short term, the label will be defined in the implementing act adopted by the EHDS Committee pursuant to article 78 of the EHDS Regulation. The QUANTUM coordinator recommended that the outputs of the QUANTUM project inform the Commission work in the preparation of the implementing act. Looking ahead, further work on the fitness-for-purpose is required to receive feedback from data users.

Reflections from Member States

Speakers: *Barbara Foley (HIQA, Ireland), Kristina Bränd Persson (National Board of Health and Welfare, Sweden) and Tijs van Gorp (Ministry of Health, Welfare and Sport, the Netherlands).*

While reflecting different stages of national preparedness, all speakers highlighted the importance of strengthening data quality as a foundation for the successful implementation of the European Health Data Space. Improving data quality is essential not only for enabling secondary use of health data but also for supporting better healthcare. Ireland highlighted that high-quality data ultimately contributes to improved patient care and emphasised the importance of coordinated implementation across Member States. To support consistent adoption of the EHDS, there is a need for aligned legislative developments, and practical guidance for data holders, recognising the diversity among data holders and that organisations differ considerably in terms of maturity, available resources and technical capabilities. Establishing a European quality improvement network was identified as one potential mechanism for supporting peer learning and the sharing of best practices.

Sweden highlighted that decentralised health information systems, the absence of formal national data quality policies and the diversity of data holders make it difficult to develop a single implementation strategy. Furthermore, the wide range of intended data uses (e.g. from routine statistics to advanced research and AI applications) means that data quality assessment must remain sufficiently flexible to accommodate different contexts while maintaining comparability across Member States.

The speakers also brought up that differing national interpretations of legislation, varying assessment procedures and differences in governance arrangements could lead to inconsistent application of the

data quality framework and unequal conditions for data access across Europe. While the future Implementing Acts will provide an important foundation, additional operational guidance, examples and sharing of best practices will be needed to achieve harmonised implementation.

The Netherlands raised some practical considerations regarding the implementation of the data quality label. A single aggregated score may not adequately reflect the complexity of dataset and its strengths and limitations, and it should not replace the dialogue between data holders and data users that is often needed to determine whether data are fit for a specific purpose. Questions were also raised regarding the definition of a "dataset", particularly in dynamic electronic health record environments where data are continuously updated, suggesting that the framework may be better suited to well-defined datasets.

Finally, multi-country studies present additional challenges for data quality assessment. Differences in national implementation, data availability, opt-out mechanisms and Secure Processing Environment arrangements may influence the comparability and usability of datasets across borders. These issues reinforce the importance of continued collaboration between Member States to develop common practices and ensure that data quality assessment results in consistent and transparent labelling of health datasets as required by the regulation.

Conclusions

Data quality assessment is crucial in secondary use, as it allows transparency and usability. The QUANTUM framework provides an important foundation for establishing a common European approach. Investment in capacity building and collaboration between Member States is needed to ensure that the framework can be applied consistently. Also support for data holders and further elaboration of the tooling of the framework would be beneficial.

Session 5. Panel discussion on EHDS governance and working structures

***Moderator**: Elina Drakvik (Sitra, Finland)*

Panellists:
Fidelia Cascini (Former Chair of the Steering Board of the Community of Practice, Italy)
Markus Kalliola (Sitra, Finland)
Dana Eleftheriadou (DG SANTE, European Commission)
Inge Franki (Health Data Agency, Belgium)

The panel discussion brought together perspectives from Member States, the EHDS2 Community of Practice and the European Commission to reflect on the implementation needs and transition towards EHDS working structures, such as the EHDS Board and technical sub-groups. The panel also discussed the learnings from the pioneering countries in secondary use, Finland and Belgium, and shared some national level developments, examples on preparedness and some implementation challenges, such as change resistance and communication challenges.

The panel also discussed the transition from the current Community of Practice towards the future EHDS Board and its working structures. Participants emphasised that the collaborative culture established through the Community of Practice should be maintained and further strengthened. Continued cooperation between Member States, European institutions and future Health Data Access Bodies will be essential for achieving a harmonised implementation of the EHDS while understanding different levels of national maturity.

One of the key messages was that the results of European projects must be effectively communicated to national authorities and future implementers of the EHDS. Considerable resources have been invested in developing guidance, technical specifications and tools through projects such as TEHDAS2 and QUANTUM. To maximise this investment, project outputs need to be actively disseminated, integrated into national implementation activities and embedded within future EHDS implementation. Without effective knowledge transfer, there is a risk that valuable experience and lessons learned will not be fully utilised.

The importance of practical implementation and peer learning were particularly highlighted. While the guidance documents provide an essential foundation, it was emphasised that successful implementation will depend on practical experience gained through multi-country pilot projects, real-world examples and continuous exchange between practitioners and authorities. EHDS2 Community of Practice and Competence Forums for peer learning were recognised as valuable mechanisms for sharing operational experiences, developing common solutions and supporting Member States, including countries with less mature implementation structures. All Member States were encouraged to actively contribute to the collaborative networks so that knowledge, good practices and status of preparedness can be shared effectively across Europe.

Finally, the importance of stakeholder engagement throughout the implementation process was highlighted. Successful governance of the EHDS requires continuous dialogue with data holders, researchers, healthcare providers, industry and citizens to ensure that implementation measures address operational needs and create tangible value for users.

Conclusions

The successful implementation of the EHDS will rely on collaboration, effective knowledge transfer and continuous peer learning. Strengthening the Communities of Practice and ensuring effective communication between European projects and national authorities require continuous efforts. In addition, meaningful stakeholder engagement and awareness raising among the variety of data holders and users are crucial to ensure operational readiness at different levels and creating a working practice on secondary use in Europe.

Session 6: EHDS Funding Opportunities

Speaker: *Mélodie Bernaux (DG SANTE, European Commission)*

Mélodie Bernaux presented an overview of the current funding and support landscape relevant to EHDS implementation, health data and AI uptake. She distinguished between actions already selected or published and broader policy orientations where no Work Programme has yet been adopted. In particular, she recalled that the EU4Health 2026 Work Programme is not yet published/adopted and that no calls, budget, eligibility, timing or scope could be announced.

The presentation covered EU4Health 2025 actions moving towards implementation, including AI for biotech, AI and health data for cardiovascular health, and direct grants to Member States for EHDS2, subject to completion of formal procedures and grant agreement signature. It also presented health-relevant actions under the Digital Europe Programme 2025-2027, including EHDS-ready digital health services, genomics, medical imaging, AI-based screening, advanced digital skills, Virtual Human Twins and relevant transversal digital enablers. Horizon Europe was presented as an important research and innovation pipeline, whose outputs may be leveraged, where appropriate, by deployment and implementation actions.

The key message was that these instruments are complementary and serve different purposes: EU4Health can support policy implementation, health-system readiness and capacity building; Digital Europe can support digital deployment and common infrastructures; Horizon Europe supports research, innovation and evidence generation; and national funding remains essential for long-term sustainability. The European Semester, and future MFF discussions were also mentioned as relevant planning and reform levers.

National funding, on the other hand, will play a critical role in ensuring the long-term operation and maintenance of the EHDS infrastructures and services in Member States. Aligning EHDS priorities with wider health system resilience, digital transformation and workforce development strategies is considered important in order to secure sustainable investment beyond individual project-based funding.

The presentation also recalled that combining instruments requires clear separation of activities, costs, beneficiaries, reporting and outputs, and must respect the prohibition of double funding.

Session 7: Update from the Capacity Building initiative

***Speaker**: Frederico Palau Arvizu*

Frederico Palau Arvizu presented an update on the Capacity Building for Secondary Uses of Health Data project, which supports Member States in preparing for the implementation of the EHDS by developing practical training and guidance to support implementation. The project has progressed from developing foundational materials towards translating identified implementation needs into concrete support activities for national authorities and future HDABs. Ongoing work includes monitoring Member State maturity, developing training materials and delivering pilot training courses to support implementation across Europe.

Several priorities were raised for the next phase of capacity building. The first is to establish a federated European approach to capacity-building resources by identifying, curating and promoting existing materials developed by Member States and European initiatives. A second priority is to expand capacity-building activities beyond the five Digital Business Capabilities currently covered by the project. Future training and guidance should also address additional operational processes such as helpdesk functions, support services for data holders and data users, scientific and ethical assessment procedures, accreditation workflows and compliance-related functions to support the full operational scope of HDABs.

Finally, it was emphasised that capacity building should extend beyond HDABs to the wider EHDS ecosystem. Data holders, data users, National Contact Points and other organisations involved in the secondary use of health data will all require appropriate knowledge and practical skills to fulfil their roles within the EHDS framework. Continued investment in training, peer learning and the sharing of reusable implementation assets was identified as a key enabler for harmonised EHDS implementation across Member States.

Cross-cutting observations and conclusions

Considerable progress is already made through European collaboration. While Member States are progressing at a different speed and adopting different organisational arrangements, it is clear that effective governance structures, sufficient resources and practical implementation support will be essential for ensuring consistent and efficient secondary use services across Europe. Strengthening the operational capacity of HDABs and sharing of good practices continues to be crucial also for the next steps of implementation. Carrying out multi-country pilot projects, more operational implementation guidance, common templates and practical repositories of use cases and challenges were identified as important measures for testing solutions and promoting consistency as the implementation progresses.

The workshop participants highlighted the importance of developing shared SPEs and advancing federated analysis capabilities to support secure cross-border use of health data. Furthermore, developing common reference architectures for SPEs and establishing harmonised privacy and security practices would be valuable to support the consistent evolution of SPEs in Member States. Significant opportunities offered by AI to support research and healthcare were recognised while emphasising that its successful deployment depends on robust governance, appropriate technical infrastructure and clear operational guidance. Investments in SPEs that are capable of supporting AI development and validation, with appropriate governance, technical safeguards, auditability and controlled output procedures will be essential for enabling responsible use of AI within the EHDS.

Another key theme was the need for greater harmonisation through collaboration. While the EHDS regulation and the implementing acts will provide the common legal framework, legislation alone will not ensure successful implementation. Continued cooperation through Communities of Practice, peer learning and structured stakeholder engagement were highlighted as core aspects for developing common interpretations, sharing operational experience and adapting implementation guidance to evolving needs. Strengthening communication between European projects, national authorities, data holders, researchers and other stakeholders will help ensure that the knowledge generated through European initiatives is translated into practical implementation and that future developments continue to respond to the needs of data users and of wider stakeholder community.

Improving data quality, interoperability and semantic harmonisation remain a prerequisite for unlocking the full potential of the secondary use of health data. Common approaches to describing data quality, harmonising terminology and improving metadata will strengthen transparency, facilitate cross-border research and increase confidence in the use of health data. Some speakers also highlighted the importance of further developing operational models that enhance transparency for citizens, including work on practical approaches for implementing opt-out mechanisms and actively communicating how health data are used to generate public value as well as increasing readiness for demonstrating the impact of EHDS.

Sustained national commitment, complemented by coordinated European funding instruments will be essential to support implementation and capacity building. Investments in training, more operational guidance and scalable tools will be needed to support both mature and less-mature Member States, while also strengthening incentives for data holders and demonstrating the value to the broader ecosystem and citizens. Importantly, the workshop demonstrated a strong commitment to making the EHDS a reality. The next steps are now crucial to gain practical experience and readiness for implementation, enabling effective secondary use of health data, and supporting better research, innovation, and policymaking, ultimately benefitting citizens and patients across Europe.

Annex – Results from action definition exercise as generated through the Wooclap exercise (all participants)

1. Actions defined by the TEHDAS2 and VALO session

Take decisions on national governance architecture / Financial issues / Clear multicountry application procedure / Clear multicountry application procedures / Pilot on multicountry application / Clarity on EU-SPE developments
Coordinate the reuse existing digital capabilities to ensure the principle develop once, use many / Develop Real Clinical Use Cases to detect hurdles and develop non binding guidelines for data standards
Ongoing collaboration of CoP community/EHDS Board
Data moves or federated model
Cross-border pilots/use cases / Enforcement practices / Capacity building and coordination across HDABs / Funding cross-country pilots / Projects working on stakeholder and citizen engagement
define and enforce data quality at individual records at data holder level - quantum good for organisation / semantic alignment across data standards to support Ai powered mapping from ehr standard and research related one / develop cost benefit model across all stakeholders - including data holders. without benefit they cannot contribute !!
Practical & realistic pilots / Data preparation environment for data holders / Pilots with SPEs to get clarity on the specifications / Realistic pilots involving active researchers / Get clarity on what constitutes a dataset
Follow up from TEHDAS 2? How does this look? / Taskforce Multi Country Application / More HDAB-level reference implementations
How to actually take steps toward mutual recognition? Especially when it comes to evaluating prohibited and allowed purposes. / What is a dataset? If it differs between MS it will make the data users work harder to find matching datasets. Also mutual recognition might get harder. / IPR&TS have not been comprehensively discussed within TEHDAS2 JA. How to make sure that one country does not overprotect the rights and big data holders relocate there.
Clear governance and attribution of roles / Sovereign technologies / IT solutions to create metadata without decoupling it from the data
Coordinating HDAB working group / EU SPE
Strategic plan , actions on governance, long term financing / Intense learning, kowledge sharing, and participation in collaboration fora / EHDS board to support needs / Development / more common use of analysis /computing methods adapted to digital data
EHDS Board sub-group Organisation / For all levels, Stakeholder Identification, outreach and prep
Pilots on different countries deciding on how to define a dataset of similar type of data, describe it, assign data quality and utility label, have it visible and user comments.
Incentives for data holders / Incentives for data holders / Business models. One price (extraction costs) brings equality, not equity. Individual researchers suffer, big pharma benefits disproportionately. / Business models. One price (extraction costs) brings equality, not equity. Individual researchers suffer, big pharma benefits disproportionately. / How to incentivise crafting the Rolex instead just the Swatch?
Connection/pathways between AI factories and EHDS (TEF? health labs?) / EU level SPE needs to be set up
Quick but qualitative adoption of the implementing acts / Public communication activities highlighting the benefits to citizens
Build scalable capacity for complex data (including genomics) / Specify minimum technical and security standards for SPEs handling omics data (compute power, storage, encryption, auditability, reproducibility) / Provide templates, tools, and support for data quality improvement and metadata harmonisation / Harmonise criteria for scientific validity, public interest, and risk assessment across HDABs / Establish a coherent national governance model: ensure alignment between GDPR, national health-data laws, and EHDS obligations / Recognise hospitals that contribute high-value datasets

(e.g., national quality labels, funding bonuses) / Participate in EU-level working groups to align SPE standards and application templates: EU CTIS for CTs- like approach / Issue EU guidance on proportionality, risk-based assessment, and safeguards for sensitive data types / Create a single EU-level template for application assessment, scientific validity, and public-interest justification / Operationalise mutual recognition through EU-level coordination, shared assessment tools, and joint review panels / Create a single EU portal for multi-country secondary-use applications / Establish permanent advisory groups for clinicians, researchers, patient organisations, and industry / Introduce harmonised EU-wide accountability mechanisms with clear enforcement tools, monitoring and proportionate sanctions to ensure consistent compliance across all Member States / Develop EU-level rules for transparency, pricing, and benefit-sharing in public–private data collaborations
roles and responsabilities need to be better defined in case data needs to travel / eIDAS compliant authentication is required for multicountry applications, at the Hdata@EU central platform (for applicants not to "disappear" during application assessment) / A better cross-talk between projects and EU initiatives: leverage what already exists to advance faster / data quality improvement stategies are crucial to in fact leverage the potential of secondary use of health data / HDABs needs guidance on how to audit QUANTUM label
/
Cataloguing data better to contribute to the EU level catalogue / At all levels, big communication efforts to ensure as many citizens as possible are informed so that they can make an informed decision. Challenge: the topic is complex.
Clear governance model, clear tasks of different actors, EHDS-board, steering group, subgroups etc.

2. Actions defined by the EU-HIP session

Decisions on organization in relation to overall national infrastructure EHDS SPEs and use cases / National decisions on organization are critical to (efficient) HDAB operations / Lessons learned / Use the expertise
Having surveillance be part of HDABs would have the advantage that the HDAB would then need to implement continuous access to data. Other parties could benefit from the capability.

3. Actions defined by the QUANTUM session

Practical implementation support & capacity building across EU / Support both Data Holder & Data Users with bridging maturity gaps, probably through intermediation entities
Showcase succesful cases of labels done / Awareness raising among data holders
Solid implementation across member states
To define what is a dataset so that each MS does it the same way.
Enable educational efforts for greater understanding and support tooling for better and uniform implementation / Validation of Quantum methods & targeted efforts (need prioritization!) / Certification
At all levels: Tying metadata and DQUL processes together. Not looking at them separately.
Tijs indicated Quantum label would suit static data sets, not dynamic data such as EHR data. Could we not have an automated mapping tool that would give results at any moment?
Find a way to operationaliseren fit4purpose / Implement transparent label validation procedures
Create an EU Academy for Health Data Governance (quality, ELSI etc) and ensure there is funding for maintenance / Create a national interoperability sandbox
QUANTUM label specifications and tool must be leveraged, used, and sustained. Support actions for implementation are needed at multiple levels (Dholders, HDABs, etc) / Data quality improvement initiatives are needed; best coordination and cross-talk between EU initiatives, to leverage and build from what already exists

Come together and jointly support the use of DQ & U label including the fitness for purpose, even though the latter one is not included in the Reg. But it's useful. / Encourage researchers to honestly share their views on the quality and utility of the datasets, even if they discovered later in their project that it may not have been the best.