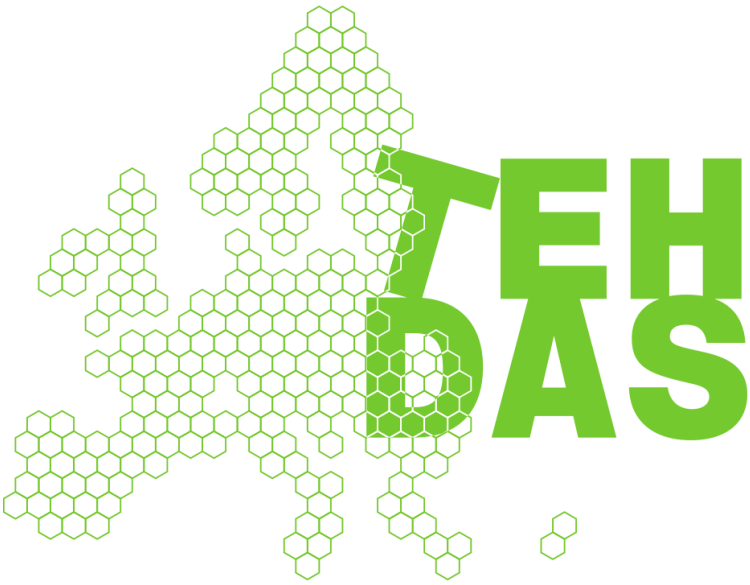

Towards European Health Data Space

Deliverable 4.3

Sustainability Plan for Secondary Use of Health Data in the European Health Data Space

29 September 2023

This project has been co-funded by the European Union's 3rd Health Programme (2014-2020) under Grant Agreement no 101035467.

0 Document info

0.1 Authors

Author	Partner
Tapani Piha	Finnish Innovation Fund Sitra
Petra Wilson	Finnish Innovation Fund Sitra
Elina Drakvik	Finnish Innovation Fund Sitra
Markus Kalliola	Finnish Innovation Fund Sitra
Linda Abboud	Sciensano
Shona Cosgrove	Sciensano
Irene Kesisoglou	Sciensano
Zdeněk Gütter	Ministry of Health of the Czech Republic
Coen van Gool	Rijksinstituut voor Volksgezondheid en Milieu
Vincent Sprengers	Rijksinstituut voor Volksgezondheid en Milieu
Mario Jendrossek	Health Data Hub, France
Tanguy Masgnaux	Health Data Hub, France
Enrique Bernal-Delgado	Instituto Aragonés de Ciencias de la Salud
Juan Gonzalez-Garcia	Instituto Aragonés de Ciencias de la Salud

0.2 Keywords

Keywords	TEHDAS, Joint Action, Health Data, Health Data Space, Data Space, HP-JA-2020-1

Accepted in Project Steering Group on 30 May 2023. The European Commission gives final approval to all joint action's deliverables.

Contents

1 Executive summary 3
2 Introduction 6
3 Methodology 7
4 The proposal for the European Health Data Space 8
5 Building sustainability of the EHDS through EU action 10
6 Building the sustainability in the Member States 12
6.1 Country examples 12
6.2 Support from the EU budget to the Member States 18
7 Specific challenges of economic sustainability of EHDS2 20
7.1 Costs for different stakeholders 20
7.2 Fees chargeable by Health Data Access Bodies 22
7.3 Towards a new health data economy through secondary use of data 26
8 The framework for recommendations on sustainability 29
8.1 Data Economy Three Stage Model 29
8.2 TEHDAS Data Lifecycle 29
8.3 Structuring the recommendations on sustainability 30
9 Recommendations 32
9.1 Establishing a clear legal basis and robust governance framework 32
9.2 Ensuring access to quality data 35
9.3 Building capacity and competence 38
9.4 Fostering trust among citizens, professionals, and policy makers 39
9.5 Ensuring adequate funding and financing 41

1 Executive summary

The proposal of the European Commission for a Regulation European Health Data Space (EHDS) is an ambitious initiative to promote the use of health data in the EU, which will demand significant political and financial investment at EU, national and local level.

Setting up a system for the wider use of health data for secondary purposes (EHDS2) will require building structures which are completely new in many Member States. In return, the benefits for research and public policy promises new advances in medicine and improvement in healthcare.

The objective of the present report is to provide background to stakeholders at EU and Member State level on developing sustainability plans for the EHDS2. It sets out recommendations for actions to be taken at Member State and EU level. It seeks to provide a pragmatic approach to addressing the sustainability needs for the EHDS2, taking account the work of TEHDAS Joint Action as a whole and in particular the results of the country visits.

The Commission's legislative proposal due to its nature makes a limited reference to the resources needed to implement the legislation at national level. However, the Commission conducted an extensive impact assessment and made funds available for the EHDS2 within the health, research and innovation budgets and the Recovery and Resilience Funds.

The national experience of setting up and running secondary use of health data is limited and countries had only limited data available relevant for the TEHDAS project. The experience of some pioneering countries as well as the work carried out in different work packages of TEHDAS allows some conclusion to be drawn.

Investments made from national budgets in three Member States studied show that major investments are needed at data holder level not only to create but also to maintain service provision. However, very limited specific budgetary data were available and so no quantitative data could be produced that could serve for other settings.

The work undertaken within the TEHDAS project shows that it is useful to look at costs and resource needs in three stages: data collection (mainly data holders), data access (data access bodies) and data use (researchers and other users).

This is described in detail by the TEHDAS Data Lifecycle model which comprises two distinct phases. The first phase is concerned with data preparation, which covers data ingestion into EHDS2 and its standardisation so that it can be made accessible. This includes also significant data curation work by data holders and health data access bodies to label data and assure its quality in order that data catalogues can be published. The second phase of the data lifecycle embodies the data users' journey. This begins with data discovery, then progress to data permit application, data use and research project execution. On completion of the research project data which have been enhanced in the research project are returned into the EHDS2, where they will re-entre the life cycle at the data standardisation phase to be re-labelled as appropriate.

The TEHDAS study on some specific challenges of the economic sustainability of EHDS2 noted that the Member States are in early phases of developing national plans and many are waiting the finalisation of the legislation before moving on.

This report found that fees charged by a health data access body cannot fully to cover the cost of their work (permits, safe processing environments). The fees are likely to be relatively small cost element for users. In contrast, the downstream cost of data acquisition from data holders can be an important element.

It became clear that sustainability of the EHDS2 cannot be studied simply as an economic question of financing and balancing financial costs with benefits but needs to be looked along five dimensions, all necessary for a sustainable system:

- Establishing a **legal basis and governance** framework
- Ensuring **access to quality data**
- Building **capacity and competence**
- Fostering **trust among citizens, professionals and policy makers**
- Developing the underlying **funding and financing** mechanisms

The 38 recommendations for sustainability actions based on the five dimensions listed above are targeted at both Members States and the EU.

The recommendations on **governance** include ensuring a smooth interaction between the EHDS Regulation and other legislation impacting data use, both EU level legislation such as GDPR and the Data Act, as well as national level legislation. This may require special guidelines to be developed in co-operation with key stakeholders and bodies such as the EDPB. It is vital to establish an EU-funded network of the HDABs, which takes forward the work on the data access process, in consultation with data holders and users.

Looking at ensuring **access to quality data**, it is noted that the legislative proposal creates a list of demands which will fall on data holders and health data access bodies. This entails investment needs for both public and private sector entities after an analysis of services to be provided. Where these tasks fall in data holders, the administrative burdens of compliance are alleviated as much as possible, and incentives are provided to guarantee their enrolment. The communication between data access bodies and data holders is vital.

The **capacity and competence** available in Member States and at EU level was identified as a critical factor but was not withing the scope of the TEHDAS Joint Action. Re- and up-skilling of staff, the identification of needs, the creation on new roles and the development of new skills will need strong initiatives both at EU and national level.

The importance of wide stakeholder engagement to build **trust** and the communication of the benefits of the secondary use of health data to citizens, data holders and data users so that the data subjects trust that their data are being used wisely, healthcare are willing to make necessary investments, and the latter make the actual use of data.

Finally, although each of the building blocks call for financial investment, it is recommended that targeted **funding and financing** mechanisms are adopted for the EHDS2, and the cost sharing principles are agreed between the Member States and the EU on cross-border use. It is of key importance that the Member States and EU work collaboratively to build up an accurate picture of the budgetary requirements of building and sustaining EHDS2. These should take account of substantive compliance costs in meeting regulatory compliance

obligations and administrative burdens, both upstream and downstream on data holders and users.

The Member States need to carry out detailed analyses for defined services so that appropriate financing allocations for their road maps can be made. Building a European data access and sharing system has a significant impact on the national data collection, access mechanism and use, their development and consequently on the costs to public stakeholders.

In this work on analysing costs and resource needs, Member States need also to look carefully at benefits, as highlighted by the Impact Assessment carried out by the European Commission. Member States can also benefit from the analyses done by a few Member States.

The consultation of stakeholders and the desk analysis showed several challenges in funding of the EHDS2 at national and EU level. The recommendations include agreeing on the principles of cost sharing between the Member States and the EU, use of varied funding instruments for EU level work, and considering later anew options for the stable maintenance of the central services.

The resource needs could be alleviated if open-source tools for EHDS2 were developed jointly, funded by various EU programmes. They could serve as the basis of common co-created solutions and would otherwise need to be set up by the Member States separately.

2 Introduction

This document describes a high-level sustainability plan for secondary use of health data under the forthcoming European Health Data Space (EHDS) Regulation. It takes the form of a series of requirements and recommendations for the secondary use of health data at national and EU level.

The term EHDS in this document refers to the European Commission's legislative proposal, while the term EHDS2 refers to the secondary use of health data[1] under the Regulation and HealthData@EU refers to the EU level infrastructure[2] connecting national contact points for secondary use of electronic health data and the central platform, through which such secondary use is foreseen to occur.

This document is concerned with the sustainability of both the EU level mechanism, as well as the national and regional level resources which must be developed and maintained in each Member State to allow the vision of EU-wide secondary use of health data within Member States and across borders to occur.

Sustainability requirements should address economic, social and ecological (environment, climate) aspects. While this document considers a broad range of requirements in setting up and maintaining the EHDS2, such as the availability of experts, engagement of professionals and trust of people in addition to economic demands, it was not possible to study all relevant social and ecological aspects.

The document presents a pragmatic approach towards the achievement and maintenance of the EHDS2 and provides recommendations on implementation of the EHDS Regulation, it considers the needs of EHDS2 and HealthData@EU infrastructure building up from the data holders and data users, through the organisational infrastructure that allows data users to securely access a wealth of electronic health data. The requirements look not only at the material needs of the data holders and users, but also at the practical and societal acceptance of the EHDS2 by citizens, healthcare professionals, researchers and policy makers that is needed to ensure that the EHDS2 is used and does not become an investment which through lack of adoption is unable to realise its considerable potential for return.

The requirements as explored focus mainly on the early development and adoption phase, but a sustainable framework for interoperability of data and for sharing of data will not be one solution fit for all situations and its development should continue over time considering also technological advances. A sustainable framework should consider all requirements, costs and resources used at various levels, from single data holders to the EU level actors.

The sustainability recommendations are built on five categories of action that are needed to build and sustain the EHDS2: legislation and governance; access to data; capacity and competence; citizens engagement and trust, and targeted funding. The recommendations based on these five dimensions is supported by more detailed analyses and models, which are described in Chapter 8 .

[1] See Chapter IV of the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space. COM(2022) 197 final.
[2] See Section 4 of Chapter IV of the proposal.

3 Methodology

The five dimensions for the recommendations were developed during the project on the basis of answers five questions provided by project partners:

- What would be the main elements for sustainability to set up and maintain the EHDS at EU and national levels, in view of the TEHDAS proposals?
- What are the types of costs for different stakeholders in the TEHDAS data lifecycle?
- What would be a sustainable economic model for the secondary use, in particular of Health Data Access Bodies (HDABs)?
- As a specific question, what is the role of the fees in the data access process?
- How can the EHDS be funded at EU and national level?

The following methodology was used to create this report:

- Desk research on sources of information in the literature and search for relevant materials available from Member States
- Information collected during the country visits[3] organised by the TEHDAS Joint Action
- Consultation of all the Work Packages of the TEHDAS Joint Action and review of their final reports for recommendations relevant to various aspects of sustainability

The sustainability recommendations set out in this document consider the sustainability needs related to the outputs from all work packages of the TEHDAS Joint Action and pay attention to the results of the country visits carried out between December 2021 to December 2022.

During the work, it became clear that there is very limited amount of relevant information available from the Member States. This is understandable due to the newness of the secondary use of health information at national level in most Member States.

[3] https://tehdas.eu/results/member-states-readiness-to-benefit-from-the-ehds-regulation-varies/

4 The proposal for the European Health Data Space

Funding needs and sources as well as benefits have been addressed in the European Commission's legislative proposal and explanatory memorandum. The accompanying impact assessment[4] provides an extensive analysis of the impacts, including all sustainability dimensions. This document only draws attention to some main points on different sustainability aspects in the legislative proposal and its accompanying documents.

The EHDS proposal is acknowledged to be very ambitious, demanding a significant investment both in terms of financial investment and of human resource both at Member State and EU Level.

The Commission's proposal for the EHDS outlines the main budgetary implications in the explanatory memorandum. Already in 2021-2022, significant funding has been made available through the EU4Health budget in the annual work programmes[5] for activities focused on the development and implementation of the EU level infrastructure, of which HealthData@EU is one element. Some of this budget has been devoted to the promotion of uptake of international data standards and various capacity building initiatives to develop the central services for secondary uses of data.

The proposal for the EHDS Regulation further calls for an allocation from the multi-annual financial framework of EUR 95.5 million in 2023-2027 for EHDS2. The European Commission suggests the to be annually 25 FTE staff within the Commission, which is not divided between the specific objectives, ie. EHDS1, EHR and EHDS2.

While allocations from the Digital Europe Programme and the EU4Health Programme will be augmented by funds from other EU sources, the proposal recognises that the development and implementation of the EHDS will require significant investments by Member States. In this context the proposal notes in particular the potential for the use of funds in the Connecting Europe Facility, Recovery and Resilience Facility and the European Regional Development Fund to support Member States in meeting some of the implementation costs of the national level infrastructure of the EHDS.

It is important to note that the legislative proposal is not designed to be an implementation plan at either EU or Member State level. At EU level, it will be supplemented by a series of implementing and delegated acts. Therefore, the details it provides on the financial and human resources for the implementation of EHDS2 and the EU level infrastructure HealthData@EU are not addressed in detail.

The proposal refers to climate impact and environmental sustainability, stating that "while new digital infrastructures and increased volumes of data traffic and storage may increase digital pollution, greater interoperability in health would largely offset such negative impacts by reducing travel-related pollution and energy and paper usage".

The impact assessment addresses a wide range of issues from economic impact to social and environmental impacts.

[4] See all documents here: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
[5] https://health.ec.europa.eu/funding/key-documents_en?f%5B0%5D=topic_topic%3A194

The economic benefits of the reuse of health data arise from efficiency savings for researchers and innovators, information transparency for policymakers and regulators and increased value for patients and healthcare providers. The benefits are estimated to be EUR 5.4 billion in the preferred Option 2, against the estimated costs of EUR 0.4-0.7 billion.

References to sustainability in the legal text

Financial sustainability is addressed in the recitals and articles which focus primarily on the potential use of fees charged by health data access bodies and single data holders.

Recital 47 notes that such fees should be chargeable in line with the Data Governance Act which sets out in Article 5 that fees shall be derived from the costs related to conducting the procedure for requests for the re-use of data and limited to the necessary costs in relation to the reproduction, provision and dissemination of data.

Article 42 of the EHDS proposal then sets out that the costs may include the costs inherent in the preparation of personal data and commercially confidential data and the maintenance of the secure processing environment. It can also cover the costs of the acquisition of data and to assist data holders in seeking consent from data subjects and permission from data holders whose rights and interests may be affected by such re-use**.**

Article 46 extends the rules on fees to costs that a health data access body may incur where a data user wishes to access data for longer than 5 years and allows health data access bodies to charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial 5 years. Article 49 extends the rights to charge fees set out in Article 42 to single data holders who make data available to a data user. Finally, on the matter of fees, Article 65 provides that the EHDS Board shall issues contributions on policies concerning fees to be charged by the health data access bodies and data holders.

A key point to note is that both the Recital and the Articles make clear that the fees chargeable are designed to cover direct costs of making data available, not to generate income for health data access bodies or data holders in a way that might off-set other costs, such as developing the infrastructure or general administrative costs.

5 Building sustainability of the EHDS through EU action

The interim report on sustainability developed by the TEHDAS Joint Action gave an overview of the funding mechanisms and possibilities of their use. It also reviewed experience of some existing projects and structures. For the details of the funding instruments referenced here, please see the TEHDAS interim report[6].

The EU has many funding and financing mechanisms beyond health, research and innovation programmes, such as loans from the European Investment Bank[7]. They have already contributed to the development of EHDS, and they will also continue to provide for further support, as described in legislative proposal and background materials. Their potential further use in digital health is summarised below but they cover many other topics as well.

Resources available in the EU multiannual financial framework

The **EU4Health** programme (2021-2027) covers a wide range of areas within health. In digital health, the programme aims to improve access to digital health services, promote the use of digital health tools and solutions, and strengthen cooperation among EU member states in the field of digital health. It supports projects run by Member State administrations, NGOs, academia, and health organisations. Support to building the EHDS is a key objective.

The **Digital Europe Programme** (DEP) supports the reinforcement of digital infrastructures underpinning the wide use of digital technologies in areas of public interest. The programme will fund, amongst other elements, tools and data infrastructures supporting data spaces in different sectors.

Building on infrastructure and pilot implementations in different sectors supported by the DEP Programme, the EU4Health Programme will focus on delivering data sharing and citizen platform applications covering areas such as secure and effective management of personal health data across borders; better data for research, disease prevention and personalised health and care; and use of digital tools for citizen empowerment and for person-centred care, in compliance with data protection rules.

Horizon Europe is the EU's key funding programme for research and innovation with a budget of EUR 96 billion for the period from 2021-2027. It funds research and innovation projects on various aspects of health: health throughout the life; environmental and social determinants of health; non-communicable and rare diseases; infectious diseases; tools, technologies and digital solutions for health and care and healthcare systems are the areas of intervention in the health cluster.

Member States could use the possibilities under the **Recovery and Resilience Facility** (RRF) and InvestEU[8] to strengthen their digital health policies and data economy. Through this fund the Commission aims to ensure a sustainable recovery that promotes green and digital transitions. This mechanism will provide financial support to reforms and investments

[6] TEHDAS. Preliminary study on funding sources and costs of secondary use of health data in the EU. Milestone 4.3, 1 April 2022.
[7] An example is E-Health Ireland, funded by the European Investment Bank in 2018.
[8] https://investeu.europa.eu/index_en

that will have a lasting impact on the growth potential and resilience of the economy of the Member States and will address challenges identified in the European Semester.

Other programmes[9] will also offer possibilities for funding initial activities around the EHDS, the new Connecting Europe Facility Programme 2 Digital (CEF Digital), the European Social Fund Plus (ESF+) and the European Regional Development Fund (ERDF).

All these funding mechanisms are important tools for setting up the EHDS and particularly the EHDS2. However, they focus on the initial development phase of the EHDS, not its sustainability in the long-term.

The exact allocation of funds to specific purposes through grants, tenders and other mechanisms will be decided in the annual work programmes of each funding programme. This will require carefully justified proposals to compete with other purposes than digital health.

[9] https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes_en

6 Building the sustainability in the Member States

European level data sharing cannot work without mature systems in Member States for data collection and access. To engage Member States in facilitating secondary use of health data, it is important that they all also develop their capacity to benefit from the use of data.

National situations with respect to readiness for secondary use of health data vary significantly from pioneering to countries still at the policy development stage. This makes creating an EU level scenario is very difficult.

The TEHDAS interim report[10] analysed the available examples on the economic aspects of the secondary use of health data from Finland, the Netherlands, and Denmark. Information on the Netherlands and Finland is elaborated in this report. They highlighted various aspects of economic impact of the secondary use of health data. Many countries, such as Belgium and Latvia, are in early stages of setting up their national structures and considering also the costs involved, and therefore limited information is available.

There is not much information available on the financing needed to meet the requirements of the EHDS2, and the TEHDAS partners were not able to add significant insight on the budget plans in their respective Member States[11]. The reason for this is primarily that at the time of developing this report most Member States had very little experience of deploying a functional health data hub, and many were waiting the outcome of the EU law making process.

In this section we describe the impact analysis from the Netherlands and experience on building a health data access body from Finland and France.

The EHDS will offer opportunities for non-Member States to participate in data collaboration, which depends on their agreements with the EU and how they implement the relevant legal instruments. This aspect, as well as the wider international collaboration, is not considered in this document.

6.1 Country examples

The Netherlands – Impact analysis of the EHDS

The Dutch example described a national investment to strengthen secondary use of health data. The government of the Netherlands awarded €69 million in 2021 to strengthen secondary use of health data through an existing collaboration called Health Research Infrastructure (Health-RI[12]), the sum gives an idea of the investment needed in a highly decentralised (and privatised) healthcare system. Health-RI is being subsidised for the duration of 8 years under the premise that the research infrastructure would then be either self-sufficient or direct funding would no longer be necessary, because the functioning of the system is embedded in national work or European systems.

[10] TEHDAS. Preliminary study on funding sources and costs of secondary use of health data in the EU. Milestone 4.3, 1 April 2022.
[11] This was also confirmed at the HIMSS Communities Deep Dive on EHDS panel on 8 June 2023, which looked at readiness of Member States to implement the EHDS2.
[12] https://www.health-ri.nl/sites/healthri/files/2021-04/Samenvatting%20Groeifondsvoorstel%20Health-RI

The Dutch government has also carried out an impact assessment of the EHDS2, the only one available to the TEHDAS Joint Action by summer 2023. Even that was carried out before the Commission made its proposal but remains the most solid analysis of the situation.

The Netherland's government has produced in 2022 the only thorough impact analysis[13] of the EHDS known to TEHDAS. The analysis (available only in Dutch) looks at legal, financial and other impacts of the EHDS proposal, immediately after the publication of the Commission proposal. It analysed impacts on the government, businesses and citizens. However, it has less information on the secondary use than other elements of the EHDS.

The Ministry of Health, Wellbeing and Sport summarised to Dutch Parliament in December 2022 the results on the secondary use as follows: The financial impact analysis estimates that the total costs for setting up and appointing a HDAB amount to EUR 3.1 – 9.2 million per participating body over a period of 5 years. This estimate consists of one-off initial costs for setting up an HDAB of EUR 0.6 and 1.7 million and the structural management costs of EUR 2.5–7.5 million per agency (0,5–1,5 million per year). This means that the final estimated initial and structural management costs depend on the number of parties that are designated as HDAB. The way in which the Netherlands shapes the HDAB needs further investigation.

In addition, the initial costs for a contact point for secondary use have been estimated 2,5 million and the yearly costs 5,5–7,5 million over 5 years. Further, a two-year information campaign is foreseen at a cost between €1 million and €3 million.

As regards business and healthcare, an assumption is that the nationwide infrastructure for primary use of health data can also support secondary use of health data. For that reason, these costs are not shown separately here. In the context of secondary use, existing initiatives such as CumuluZ and HealthRI can also be used.

The initial costs for data holders of making data available for secondary use are estimated at €7 million to €12 million. These initial costs are incurred for training personnel in the context of the delivery and assessment of (enriched) datasets. The structural costs for data holders are estimated to be €119 to €239 million over a five-year period. The final structural costs are limited because it is assumed that a fee can be charged for a large part of these costs.

No obligations and associated costs arise for citizens from the EHDS, although the EHDS does contain several rights for citizens.

Benefits for each three groups are estimated in qualitative terms.

Finland – early experience on a health data access body

Finland has been the forerunner in setting up a GDPR-compliant, nationwide system of secondary use of health data. The original assessment in the proposal of the Finnish government was relatively broad, as no experience was available in advance. The data available of the first years will help to make a better assessment of the longer-term costs.

[13] Ministry of Health, Welfare and Sport (VWS). Financial impact analysis of the European Health Data Space, 25 November 2022 (report in Dutch only).

Finland provides an example of the functioning data access and permit authority since 2020 and it is possible to estimate the costs of health data management in the second stage. Table 1 gives an overview of the budgeted and real costs and income[14].

Table 1. Findata's budget allocation, estimated and real costs and income in 2019-2024.

	Cost and income in the state budget (1 000 €)			Real cost and income (1 000 €)	
Year	**Final budget allocation**	**Estimated costs**	**Estimated income**	**Costs**	**Income**
2019	2 500	2 500		506	0
2020	5 200	5 250	50	1 782	105
2021	3 200	3 675	475	2 543	276
2022	2 200	2 630	430	2 929	655
2023	2 200	2 630	430	…	…
2024	2 200	2 795	595	…	…

The early budget figures were significantly adjusted in the yearly budget procedure. The difference in the budgeted and real costs and income shows also the difficulty to estimate the costs at the beginning of the operation. However, the later years start to give a good indication of the order of magnitude of the costs to operate a national data permit and access authority.

Findata is participating in two EU co-funded projects: the TEHDAS Joint Action (2020-2023) and HealthData@EU Pilot (2022-2024). Their total cost has been 23 000 € and 210 000 €, which includes the 40% national co-funding. The FinHITS direct grant, being negotiated, would run 2023-2027. The EU support would be annually around 300 000 €.

Findata has published its annual reports in English on its webpages[15], which give a good insight into Findata's operations. In 2022, Findata received a total of 270 applications (312 in 2021) and made a total of 284 decisions (262 in 2021). The processing time for information permit applications ranged from 1 to 427 days, the median was 79 days (80 days in 2021).

Findata provides a secure operating environment, called Kapseli. There were 113 Kapselis at the end of 2022 (52 in 2021), with a total of 830 users (371 in 2021). In total, EUR 229 000 were paid for their use.

According to the published information[16] at the end of 2020, the cost of Findata's decision on an data request or a permit was € 1,000 for an EU applicant. Findata charged € 115 per hour for its data processing such as combining data sets Findata's data processing fees had been from € 115 to € 4,900.

[14] The figures are from the budget tables of the Finnish Government (in Finnish) and the annual reports of THL, to which Findata belongs for administrative purposes.
[15] https://findata.fi/en/about-findata/annual-report-2022/
[16] Findata director Johanna Seppänen in the Finnish Medical Journal 2020:75:2574-8 (in Finnish) and calculations for the Findata pages.

Data controllers determined how much they charged for data retrieval. Data controllers had requested from € 0 to € 69,000 for the data retrieval.

Findata charged € 190–300 per month for the use of the remote access environment.

In 2022, the average of 10 most used data providers charged € 3 500 per request, however, healthcare organisations charged on average € 6 200 and government agencies € 2 200 per request, which may reflect the more complex nature of healthcare data.

Finnish experiences on fees are further discussed in Chapter 7.2 .

Findata has a lean organisation[17], consisting of three units (Figure 1). From 1 person in May 2019, Findata's staff has increased to 25 in August 2021 and to the current 27 by August 2022. Of them, 7 are in Management Group and 20 in Data Services.

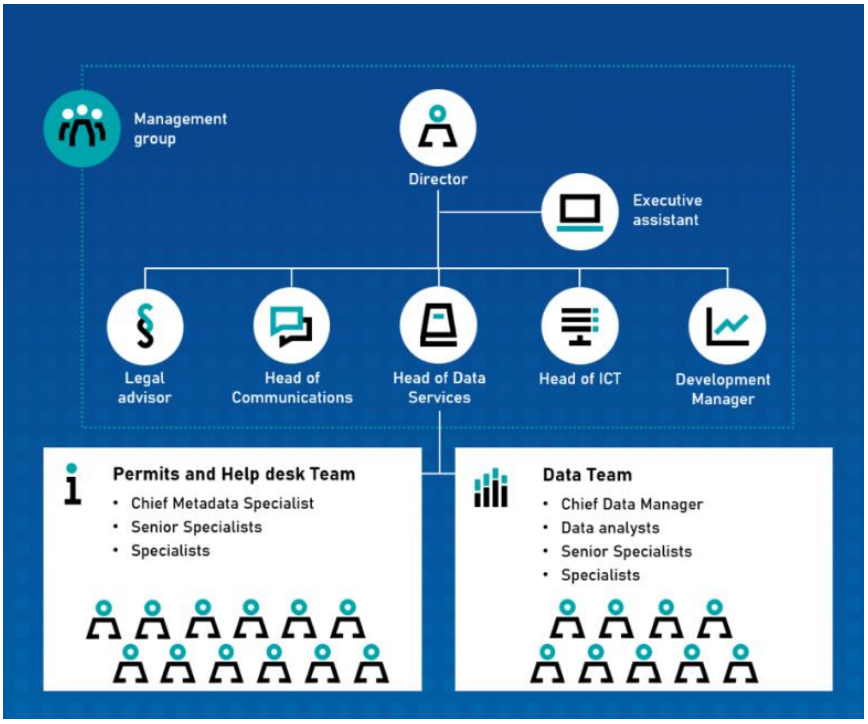

Figure 1. Findata organisation

The personnel costs of Findata in 2022 were EUR 1.4 million and services purchased were EUR 1.1 million.

The discussion of Findata among researchers has been partly critical as the Act on secondary use of social and health data changed many existing practices. Before the Act, quite a large part of the costs related to R&D activities remained hidden. Findata has made them visible. In addition, secure operating environments have increased the costs.

Therefore an external report[18] on Findata's operation recommended organising discussions on the principles on the costs of secondary use to form a national consensus on what data

[17] https://findata.fi/en/about-findata/#organisation
[18] Gesund Partners. Report on measures to support the Act on secondary use of social and health data February 2022. Report in Finnish only.

should cost and how secondary use (especially academic research activities) is financed. The report also called for a more detailed analysis of cost components of the secondary use.

The analysis of the Finnish government on the economic effects of the EHDS

In its analysis[19] of the economic and administrative effects of the EHDS proposal, the Finnish government first notes the support from the EU budget from the EU4HEALTH and Digital Europe programmes, among others, as well as the support from the Recovery and Resilience Fund. However, it points to the self-financing required. Another challenge might arise from the shortage of skilled workers as many resources are tied up in national development work linked to the reform of health and social care.

The Finnish government estimates that updating several laws and regulations will require several, even 6 – 8 FTE years from the Ministry of Social Affairs and Health, and their cost is estimated at around 600,000–800,000 euros.

With regard to the secondary use of health data, the regulation would have financial effects on the national permit authorities and data holders and on data secure operating environments. The government notes that in terms of secondary use, Finland is in a good position as structures required by EHDS already exist and are being developed. The additional investment depends on the final content of the regulation.

The government estimates that changing regulations, guidelines and operating models of Findata, other permit authorities and data holders will cause one-off costs of around EUR 10-12 million. In addition, the annual costs are estimated to increase EUR to 5-6 million per year due to the increased workload. Further, a one-time investment of EUR 9-10 million is needed for data transfer of data controllers, data processing of permit authorities and for secure operating environments. The annual operating costs are estimated to increase by EUR 0.3–0.5 million.

The EHDS regulation would also affect the fees charged to researchers and other customers who need information. At least part of the investment costs and the increase in operating costs would have to be paid by customers in the form of increased permit and service fees.

The Office of Data Protection Ombudsman estimated a significant new workload due to supervision ad increased complaints (not quantified). The increase is due to, among other things, cooperation obligations with other authorities and bodies responsible for access to health information and the new rights for patients.

[19] Notice of the Government to Parliament on the Commission's proposal for a regulation on the European health data space. U 61/2022 vp. In Finnish and Swedish only.

France – a growing agency as another model for a health data access body

The French Health Data Hub (HDH) is another agency that carries out functions of a future health data access body.

Table 3 summarises HDH expenditures between its creation in 2019 and 2022, the last year for which full spending records are available. The expenditures are expected to further increase over the next few years as the organisation grows larger in terms of human resources but also increases operating costs (e.g. cloud infrastructure).

Table 2. The expenditure of the French Health Data Hub (HDH) in 2019-2022.

Costs in 1 000 €	2019*	2020	2021	2022
HR costs	127	3 189	5 187	6 674
Other operating costs	1 464	8 001	9 172	11 155
TOTAL	1 591	11 189	14 359	17 830

*The organisation was set up during the year.

HDH's revenues are by a large majority from public sources. Most revenues are and will be provided through the social security fund. In the initial phase of creating the organisation, HDH benefited from funding from the public action transformation fund (FTAP) in addition to its other revenue streams. In addition to these major funding mechanisms, HDH's revenues include membership fees of the organisations present in its governance bodies and European project-based funding.

Human resources are shown in Table 4 and their distribution in Table 5. It should be kept in mind that the tasks and responsibilities of Findata and HDH are different. They provide different services and fulfil different functions of the TEHDAS Data Lifecycle (see Section 8.2), and of course their potential clientele is of different order of magnitude.

Table 3. The number and full-time equivalents (FTE) of staff of the French Health Data Hub in 2019-2025.

	2019*	2020	2021	2022	2023*	2025*
Full-time equivalents	20	34,1	56,6	69,0	…	…
Number staff end of year	20	54	58	89	122	141

*Projections.

Table 4. The projected distribution of staff of the French Health Data Hub at the end of 2023 and 2025.

Type of Department	Department	2023	2025
General Direction	Management and institutional relations	3	4
Technical	Technical and platform development	20	23
	Partnerships	13	18
	Data	24	27
	Data access	7	8
	Projects and user services	8	10
Strategic	Scientific	13	15
	Medical	3	3
	Citizen	3	3
Support	Secretariat, HR, Finance	9	11
	Legal	10	11
	IT Security	3	4
	Communication	6	6
TOTAL		122	143

6.2 Support from the EU budget to the Member States

The Commission estimates in the budgetary implications section of the explanatory memorandum that EUR 96 million will be allocated specifically for EU level infrastructure for the secondary use of data to cover HealthData@EU and Member States audits for the connection nodes.

The creation of data nodes or Health Data Access Bodies are supported by direct grants to Member States, which will be used for setting up services by Health Data Access Bodies.

For the further costs at Member State level, the proposal indicates that the costs for the connection of Member States to the European infrastructures within the EHDS will be partially covered by EU funding programmes that will complement EU4Health, such as Recovery and Resilience Facility and the European Regional Development Fund. In addition, various budget lines under Digital Europe Programme, Connecting Europe Facility and Horizon Europe will be used to build up data resources and data access mechanisms. Other EU budgets will be used to develop fields generic to the data economy such as AI and 5G, while others will focus on health sector specific such as genomics and cancer.

A significant cost burden could also arise for the producers and providers of new EHDS conformant EHR systems. While the improvement of the EHR systems will be mainly serve

their primary purpose, some costs relate to enabling smooth secondary use of data. They will in due course pass the cost on to public bodies in the price of EHR systems.

The impact assessment undertaken by the European Commission discusses both primary and secondary use at EU and national level. Looking at national level investments needed the impact assessment states that around half of Member States already have systems allowing to share patients' data between healthcare providers, whilst several others are in the process of strengthening the level of digitalisation supported by national and EU funds. It is noted that almost EUR 12 billion have been negotiated by the Commission and Member States under Recovery and Resilience Facility in this area, and it is concluded that "therefore, the EU funding is expected to cover most (if not fully) the national effort for digitalisation that would be needed to support patients' control over their own health data".

Looking at the economic demands for secondary use, the impact assessment states that the costs of creating health data access bodies and systems will vary greatly between Member States, not least because some already have bodies in place and operational. In making the economic assessment for Member States which must build a new access system, the assessment assumes that Member States would need to invest between 4 and 50 FTE staff members to run a health data hub, as well as costs of the data access infrastructure. This, it is assumed, will be shared with other data spaces foreseen in the Data Governance Act. The latter estimates a set up cost of EUR 10.6 million and a maintenance cost of EUR 0.6 million yearly per secure data processing environment.

Looking at the potential for offsetting these costs, the impact assessment cites the example of Findata and calculates that the income from fees could amount to EUR 92-166 million across the EU in the baseline scenario, and EUR 36-58 million in the preferred Option 2.

As noted in the impact assessment, the funding available from the EU budget will not be sufficient to allow Member States to set up and maintain their health data access bodies. The Member States will need to work out their economic and funding models to establish both the costs and the potential benefits of the national level infrastructure, data access bodies and governance schemes, and then to connect those to the EU level EHDS. Some of these costs would fall on public budgets, notably those related to the health data access bodies.

7 Specific challenges of economic sustainability of EHDS2

While there is little quantified data is available on countries' experiences to date, and Member States have only recently begun to develop plans to budget for the financial and organisational requirements for meeting their future obligations under the EHDS Regulation, some issues arose repeatedly in the discussions.

The following sections look at three of those issues: costs for different stakeholders, fees chargeable by health data access bodies, and a broader policy issues in the health data economy.

7.1 Costs for different stakeholders

The definition of secondary use of data implies that data were collected originally for another purpose, such as for care provision, clinical trial or disease registries. Most costs of obtaining data will be borne by those seeking to use the data for their primary purpose. But enabling the secondary use adds further needs to the health data processing system.

Understanding the structure of costs helps to estimate resources needed. In undertaking such work, it may be useful to use the OECD guide on cost categories[20] for organisations adopting strategies to comply with new regulatory requirements. These include the cost that are incurred by businesses or other actors who are required to comply with regulation, as well as the costs to government of regulatory administration and enforcement. The costs are termed substantive compliance costs and administrative burdens, which both apply to public and private bodies. The easy-to-calculate costs will be the most visible but not always the largest.

The costs for HDABs related to data collection into the EHDS2 are the costs of rendering the data provided by primary data holders into data sets which are quality assured and searchable. This demands data curation, labelling and collecting into databases which can be accessed in the secure data processing environments. While the EHDS Regulation may in the end put lighter requirements, going beyond the core demands will enable Member States to reap the full benefits of implementing EHDS2. The Regulation requires:

- The preparation of metadata catalogues (Publication phase in TEHDAS Data Lifecycle, Figure 3, see Section 8.2). This obligation ensures the discovery of data but its implementation will require competence and capacity.
- The transfer of data from a data holder to the Secure Processing Environment (SPE) (Use phase in the TEHDAS Data Lifecycle). This also will require competence and capacity. Potential harmonisation of data before its deposition at a SPE will be required, or this responsibility will be shared with HDABs.
- Systems to facilitate interaction with citizens to exercise their rights (consent or opt-out depending on the outcome of the legislative procedures at EU and national level). While not yet clear, for example hospitals as one of the typical data holders will be the front line interacting with citizens and patients.

[20] available at https://knowww.eu/nodes/5dfa21a18db69db83e0ef918

Some of these costs will fall on health data access bodies and may be defrayed by wider adoption of data standardisation tools by primary data users, such as the maintenance cost using EU standards OMOP, HL7 and other data semantic standardisation tools and technologies. However, the initial investment in new national data access systems, or the adaptation of existing system, will be high. Nevertheless, they represent only a share of the costs of the governance and capacity elements of ensuring a trusted EHDS2 environment.

The financial impact on health data access bodies is hard to estimate but based on the reports of Finland, Denmark and Netherlands, the costs of running a secure processing environment, including data protection, data anonymisation, and security infrastructure and governance, will be significant.

The cost impact of the EHDS2 on the data users, e.g. researchers, is also difficult to estimate. There are factors that might lower the costs of data access and use, such as a one-stop shop for permits and standardised data access processes. However, the increase in data quality and security as well as better scrutiny of data access applications in new systems may be reflected in the costs and consequently fees. The more regulated system will make some previously invisible costs visible. Fees for permits and for data acquisition processes could impact users significantly. There have been fears of delays in granting of the permits and indeed the waiting time can be costly for data users. However, once the EHDS2 works well, the benefits for end users will outweigh the costs in terms of financial and time costs as well as data quality.

Staff costs will arise predominantly in the public sector but where data holders are private sector entities, they too will incur costs in complying with obligations to make data available to health data access bodies. Further, private sector data holders fear that they will lose financially and competitively if the intellectual property inherent in the data they provide the HDABs is not adequately protected. The proposed legislation addresses the issue, but anxiety still exits that it might not be sufficient.

There is no assessment available of the costs in making data from EHRs and other sources usable with a health data access system. Currently, such data curation is a successful business for several enterprises in Europe and worldwide. Curation of data is costly but also necessary if data users are to gain real benefit from data access.

It is important to note that the costs incurred during the TEHDAS Data Lifecycle (such as standardisation, publication, discovery, use and finalisation) can be allocated in various ways to actors involved. This will be to a large extent a policy question at national level.

While real costs for different stakeholders are not available, the input provided by TEHDAS partners allows an estimation of the relative impact of key aspects of the creation and maintenance of the EHDS2, as shown in Table 6.

Table 5. Broad categories of costs for the creation and maintenance of the EHDS2 and estimation of their financial importance.

Stage	Main stakeholders	Share of all national EHDS2 cost	Source of costs to optimise the system for the EHDS2	Funding and financing sources	Availability of cost information
Data collection	Healthcare, hospitals and health centres, other data controllers	Considerable	Modifying the system of data holders ready for access and secondary use and maintaining the capability for secondary use. Possibly modifying the data structures and semantics. Making the data available.	Data holders' operating budget. Some support may be available from EU level funds (RFF). EU level standardisation and tools will help.	Only general estimates could be produced to give an order of magnitude
Data access	HDABs, national authorities	Modest	Higher in the start-up phase as the access models and tools are developed.	National budgets. Some support from EU level funds, notably EU4Health. Some costs recouped through fees charged to users.	Some specific costs shown in Section 4 for Finland and Annex 2. Waiting other countries to provide cost estimates.
Data use	Researchers in academia, public and private sector.	Medium	The costs for data users depend on how much the data holders seek to pass on to the users. Costs depend also on fee policies.	Costs should be included in the research budgets and taken into account in grants, including from the EU.	Only general estimates and some statistics from Finland.

7.2 Fees chargeable by Health Data Access Bodies

The EHDS proposal allows in Article 42 that HDABs (and also single data holders) may charge fees for making data available for secondary use, providing that such fees are proportionate to the costs of making the data available for secondary use.

Article 42 states however that fees must be adjusted to ensure that SMEs, educational establishments, public research bodies and other similar organisations shall be taken into account when fees are set.

In the earlier years of a HDAB's operations when significant initial investment and training costs will be incurred, the burden of such costs will fall mainly on the public purse. It is therefore of great importance that the costs of making data available for secondary use are assessed as fully as possible by both Member States and the EU institutions to allow for adequate funds to be made available.

There is much discussion on fees and fee structures at EU level and they are likely to cause much debate also at national level. The Commission proposal is clear on the possibility of using the fees and the final outcome will dictate the freedom of Member States to set the fee

structure. There have been ideas on tiered fees depending on the quality of data or the financial capacity of the user. However, national[21] and EU[22] frameworks may also set the limits for the possibilities.

TEHDAS sought to carry out a comparison of fees in four countries[23], but it proved to be fairly complicated due to the widely differing fee practices. An example of prices for a package of 3 datasets for 2 years resulted in 16 000 € in Finland and 20 000 € in the UK, it was not possible to determine for Denmark and France.

For the moment, the French Health Data Hub does not charge fees to its users[24], but this can change in the future. Although the HDH does not charge fees, some data holders charge data users for access data through other platforms than the HDH's platform.

The experience of Finland's operation of Findata since 2020 indicates that fees are a source of funding but are not sufficient to cover the costs of running a successful health data access body. The Findata experience has demonstrated that a HDAB is a necessary part of a public health systems infrastructure which requires public funding. The Findata fees are extensively described on their webpages[25].

The 2022 annual report by Findata[26] showed that a total of EUR 1.74 million was paid for the secondary use of social welfare and health care data through Findata in 2022. On average, only 22% of the fees collected from customers consisted of Findata's decision fee and the costs of processing the material. The Findata processing costs arise from combining data sets collected from controllers, pseudonymisation or anonymisation, and delivering the data to a secure operating environment. As much as 78% of the total bill paid by the customer consisted of data extraction costs charged by data controllers.

Further, the users paid EUR 229 000 to Findata for the Kapseli secure processing environment. As there are eight other safe processing environments in Finland, many researchers used other SPEs.

[21] In Finland, Act on the basis of fee chargeable by government bodies (150/1992) applies also to Findata.
[22] The EU Data Governance Act (2022/868) discusses the fees in Article 6.
[23] The unpublished note is available from the TEHDAS secretariat at request.
[24] Information from the French HDH.
[25] https://findata.fi/en/pricing/
[26] https://findata.fi/en/about-findata/annual-report-2022/#Distribution-of-costs

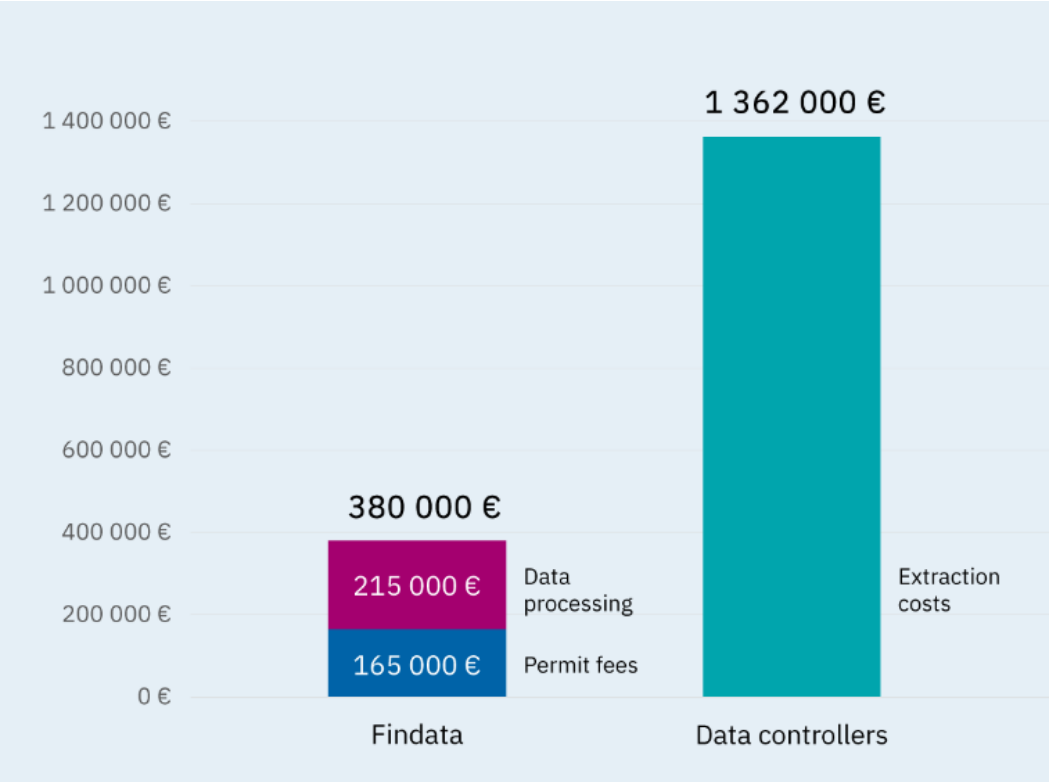

Figure 2. Findata's permit and data processing fees and data controllers' extraction costs in 2022. Copied from Findata's webpages.

It should be noted that the total costs of Findata in 2022 were EUR 2.55 million, of which personnel was EUR 1.43 million and services purchased EUR 1.09 million (information by email).

The experience from Findata draws attention to three issues:

- The user charges have caused much discussion in Finland. In particular, clinical researchers have seen the costs of data access through Findata as a significant obstacle. This is partly due to that the new system has made costs of data acquisition more visible. Previously hidden expenses charged by data holders have been made transparent. On the other hand, other researchers and in particular bigger entities have been satisfied with a smooth operation of the "one-stop shop". Some of the discussion was related to the teething problems of a new system.
- Findata charges users for the data permit, for curating the data and for providing the safe processing environment. These have not been the most significant cost elements for data users, the bulk of the cost has resulted from the downstream cost of the data holders charging to make the data available[27]
- In 2022, Findata's all income, mainly user charges, covered 21% of the EUR 2.8 million total budget of Findata. The rest was covered with direct government budget funding.

[27] Seppälä J. Article. Finnish Medical Journal 2022 (in Finnish)

TEHDAS studied the legislation in place or being developed[28] in several countries. The interviews and surveys on national legislation found that most of the countries that either have established or are in the process of establishing national nodes managing processes for secondary use of health data, have in their national legislation permitted such authorities to charge fees for their services or enabled them to establish companies under their remit for selling additional services.

The fees charged may be attached to services where they gather, categorise, refine or prepare data before handing out the data sets. In some cases, fees also apply when data is gathered from different data holders to be integrated. However, most authorities and organisations have not yet started using the possibilities to charge fees or set up additional services. Their focus has been to get their organisation in place and be able to offer the initial basic services. The primary focus has been to enable secondary use and only then look at the potential of the economic models that will be necessary to keep the system running.

During the country visits, the following comments were made regarding fees:

- Many countries agreed with the possibility of setting fee policies to support services (e.g., provision of a secure processing environment) or for the work done to provide access to data (e.g., pseudonymisation, retrieval of appropriate datasets). Countries noted that fees should not be charged for the data itself, due to arguments regarding data ownership and the value of data. Fees must be justified, harmonised and transparent (and predictable).
- Conversely, some countries expressed concern that fees could be a barrier to research and preferred a model where the EHDS and access to health data is free for researchers and policymakers.
- Some countries noted that to support innovation, European funding should go to the innovators who have to pay the charges.
- It is important to clarify the governance of fee policies, for instance what level/institute has the mandate to implement them, or how to harmonise fees across countries.
- Countries agreed that improved processes for data collection and provision generally lead to decreased work needed for data preparation etc., which should lower fees. Further discussion is needed on how to balance the increased investment to improve those processes *vis-a-vis* lower resulting fees, and at what level the financial gains/losses are experienced as well as assessing the benefits flowing from improved use of health data.
- Many countries expressed preference for differential fees for industry and academic researchers, but without preferential access for higher fees.

The fee concept included in the legislative proposal is useful in terms of addressing the costs that will arise for data holders in responding to data requests. However, fees alone will not

[28] TEHDAS. Recommendations for European countries when planning national legislation on secondary use of health data. TEHDAS D5.2, 1 March 2023.

be enough to build and sustain all the components of the EHDS2 which must be created and maintained at Member State level.

7.3 Towards a new health data economy through secondary use of data

The future EHDS2 will foster health data economy in the European Union. Its implementation has many aspects that are not directly related to its operational implementation, but which will be relevant in the policy making process. These include identifying the benefits and potential return on investment that secondary use of data could generate.

The European Commission has estimated the benefits of its proposal in the impact assessment[29]: in the preferred option (2+) the benefits amount to EUR 5 416 million over the baseline, while the costs range from EUR 351-743 million.

The benefits of better secondary use of health data result from improvements in data management and increased use of data. The calculations are typically based on various assumptions and the benefits are impossible to measure directly. It would, however, be crucial to make the benefits visible in the public discussion. The benefits may be obscured as they are diffused across many users and over time, while the costs are often immediately visible.

The review[30] by the European Commission's Research, Innovation, and Science Policy Experts (RISE) looked in 2015 at the pathways generating value and what is known about the value of research. It noted that there is overwhelming evidence to justify research as one of the best investments that can be made with public (and private) funds. Rates of return are of the order of 20-50%. It also argued that the benefits of research go well beyond the radical paradigm-setting innovations. The report reiterated that the value of research is not only economic. There is a direct contribution to societal challenges. Beyond that research is a part of the culture of Europe and should be valued for its role in creating a critical and reflexive society.

Like many other researchers, the RAND experts[31] noted that the literature on health data generation and use has identified a myriad of potential social and economic benefits from health data use. They include potential benefits for R&D and innovation, for public health and pharmacovigilance, and for healthcare delivery and the wider health system.

The European Parliament's research paper[32] on EHDS argued that the economic benefits of aggregating data from multiple sources for research and public health planning are clear, notably including faster and more cost-effective development of new drugs and medical procedures and achieving better public health decisions. The study emphasises that future

[29] SWD(2022) 131 final, page 69.
[30] Luke Georghiou. Value of Research. Policy Paper by the Research, Innovation, and Science Policy Experts (RISE). European Commission, RISE, June 2015.
[31] Sonja Marjanovic*, Ioana Ghiga*, Miaoqing Yang, Anna Knack. Understanding value in health data ecosystems. A review of current evidence and ways forward. Rand Europe 2017.
[32] J. Scott MARCUS, Bertin MARTENS, Christophe CARUGATI, Anne BUCHER, Ilsa GODLOVITCH. The European Health Data Space. A study at the request of the committee on Industry, Research and Energy (ITRE). European Parliament, Policy Department for Economic, Scientific and Quality of Life Policies, 2022.

benefits from secondary use of health data for innovation purposes are inherently difficult to quantify. However, they consider that cost savings and benefits as estimated in the impact assessments are of a plausible order of magnitude. They also argue for taking into account the non-monetised benefits and discuss the fairness of sharing the costs and benefits.

The creation of EHDS2 introduces a new paradigm in the European health data economy in which data generated within the publicly funded care systems are more easily made available for re-use by both public and private actors to boost research and innovation. In Europe, the investment and operational costs for making data available for secondary use will be financed mainly by the public sector. The challenge is to establish diverse sources of financing since Europe's stretched healthcare systems are unlikely to be able to fund all the investments needed.

The financing of the use of secondary use of health data, including establishing of the national infrastructure, calls for cross-sectoral understanding on the national level. This will represent a new task for EU Member States that must be well prepared and then effectively performed, also considering the terms for entry into application of relevant provisions of the Regulation on the EHDS.

It is important to address the concerns expressed by researchers and healthcare professional as well as local, regional and national policy makers about cost implications of creating EHDS for both primary and secondary use of data.

When considering costs and benefits of sharing of health data for secondary purposes, healthcare providers and professionals are asked to perform tasks which will not always directly benefit them as data holders. The tasks may not fit their current infrastructures by design and the professionals may not have all the necessary skills and capacities. Data holders are most likely expected by national authorities to so increase the quality of their data, possibly better than needed for primary purpose. This is also necessary for reaping the full benefits of the secondary use of health data.

Geographical and global aspects of data sharing for secondary purposes cannot be sidelined. Repurposing healthcare data so that it can be used for research will bring new and better products and procedures to the healthcare market if there are companies that are capable of seizing the opportunity and developing those. The maturity of national health information systems and business ecosystems play a crucial role. To ensure support from all the Member States, the fair and equitable sharing of benefits and costs is important. Wider cooperation between Member States would help all of them develop their system in order to benefit from the new availability of health data.

A question that will inevitably be raised is who benefits from the European efforts to make health data available. Will European health data be used primarily by European or global industries[33] [34]. For the acceptance of the EHDS, it is important that national and local economies across the Member States benefit from the health data made available. National

[33] Ashleigh Furlong. The EU's new health data space is coming and industry wants in. Politico 27 October 2022.
[34] Terzis, Petros. "Compromises and Asymmetries in the European Health Data Space". European Journal of Health Law 30.3.2022 (pages 345-363). https://doi.org/10.1163/15718093-bja10099. See in particular Chapter 4.1.

and local healthcare providers and authorities will understand the new data economy if they see companies benefiting from the EHDS in their regions. The data holders and citizens typically think first locally, regionally, or nationally.

The RISE report also addressed the question of how local and possibly remote economies can benefit. The report underlined that performing research is the most effective way to ensure that local economies can stay in touch. The more peripheral is the region the stronger is this imperative.

While TEHDAS has concentrated on the data access stage in the Three Stage model (see the next chapter), and it has discussed the implications to the data collection stage, the value of the EHDS2 will be created in the third stage, the use of data. Data users are typically researchers in academia or business and their success will determine the success of the EHDS2. The use of the EHDS2 will determine its contribution to research and innovation.

8 The framework for recommendations on sustainability

To develop recommendations on the sustainability of the EHDS2, the TEHDAS Joint Action partners worked on the basis of several models developed for different purposes.

These include the three stage **Data Economy Model** and the **Data Lifecycle Model,** which comprises six elements. These models are outlined below to show the thinking behind the recommendations of this report.

8.1 Data Economy Three Stage Model

The earlier TEHDAS work[35] developed a three-stage model of the data economy as shown below.

Figure 3. Three stages in the use of data in the data economy

The first stage is data collection that is carried out for the primary purpose of the data use. Data collection does not necessarily take into account the secondary use of data. In this first stage only those costs that relate to making the collected data fit for the secondary use are relevant in the context of secondary use. This can include structuring the data and increasing its quality. But when secondary use of health data is well organised, it will include developing the technical infrastructure, semantics used and organisational support.

All elements in the second stage, and some elements of the third stage are detailed in the users' journey and the related services, are relevant for the sustainability analysis. However, not all elements of the third stage are a part of the user journey, since the third stage is wider than the actual analysis of the data for research or other secondary purposes.

The elements of the last stage, funding of research or costs of the data analysis in public administration or within companies, also fall largely outside the scope of the TEHDAS Joint Action and consequently this document. However, data use in the context of the EHDS2 may contain services which traditionally were seen to be within the remit of the research process itself, as described in the next section.

8.2 TEHDAS Data Lifecycle

TEHDAS has produced a model for the data life cycle (Figure 4), which helps in analysing the stages and services necessary in the data sharing operations. TEHDAS has also defined[36] the necessary services during the data life cycle. They enable detailed calculations of costs and benefits in the next stages.

[35] TEHDAS. Preliminary study on funding sources and costs of secondary use of health data in the EU. Milestone M4.3, 1 April 2022.
[36] TEHDAS. Options for the minimum set of services for secondary use of health data in the EHDS. TEHDAS D7.1, 5 April 2022.

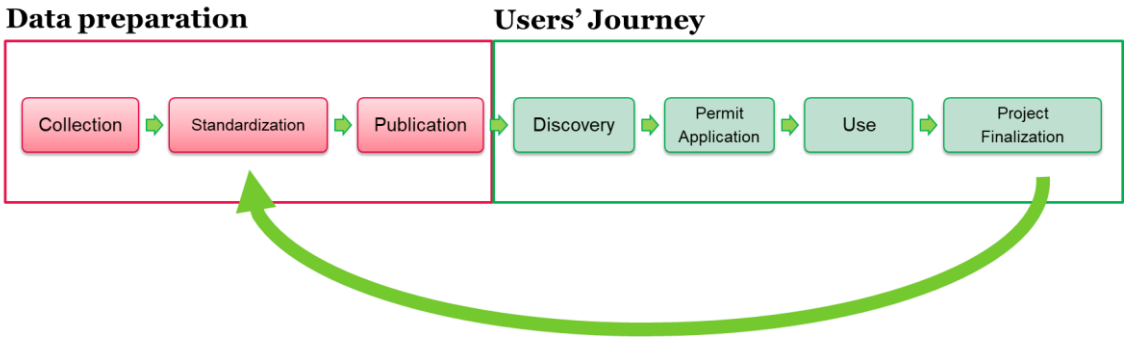

Figure 4. TEHDAS model for data lifecycle for the EHDS2

The TEHDAS Data Users' Journey and its further refinement as the overall Data Lifecyle, including the related services, have been extensively described in other TEHDAS documents (Users' Journey[37] and Data Lifecycle[38] [39]). That can be used as a starting point of analysing the costs of setting up and running different services to be provided by the EHDS2 nodes. Those services are essential in discovery the existing data, negotiating the access to and using it.

A simple mapping can be done between the TEHDAS data lifecycle and the Data Economy Three Stage Model: Collection, Standardisation and Publication phases of the lifecycle are comprised as 'Data Collection' in the Three Stage Model; Discovery and Permit Application phases correspond to the 'Data access'; and use and project finalization phases correspond to the 'Data use'.

8.3 Structuring the recommendations on sustainability

During the work on this document, it became clear that costs and financing are not the only dimensions relevant to sustainability of the EHDS2 and it is necessary to consider other aspects beyond cost and financing. Notably, other EU projects[40] [41] have come to the same conclusion and have developed commentary on sustainability that addresses a wider set of issues than financial investment.

Building on the models presented above, TEHDAS agreed on five dimensions for sustainability recommendations, which explore the implications of developing and maintaining EHDS2 both at EU and national level. The dimensions also indicate cost

[37] TEHDAS. Options for the minimum set of services for secondary use of health data in the EHDS. TEHDAS D7.1, 5 April 2022
[38] TEHDAS. Report on architecture and infrastructure options to support EHDS services for secondary use of data. TEHDAS M7.6, 24 March 2023.
[39] TEHDAS. Options for the services and services architecture and infrastructure for secondary use of data in the EHDS. TEHDAS D7.2, 4 July 2023.
[40] The B1MG project suggested four dimensions: Financial, legal, governance and data access dimension. D6.8 Policy briefs —1v0, 2021.
[41] eHAction Joint Action suggested nine core elements: People Empowerment and Access, eSkills for Professionals, Interoperability (EHRxF), Infrastructure, Cybersecurity/Security, Enterprise Architecture, Coordination and Governance Model, Innovation (CSS – common semantic strategy), Legal Challenges. D8.3 - Sustainability plan and recommendations, 2021.

groupings which must be financially supported at EU and national level for the EHDS2 to be built and sustained.

The five sustainability dimensions (Figure 5) can be described as follows:

- Legal basis for data use, robust governance and diligent data protection – enforce the rules of the system, enable its actors and ensure the prudent use of data.
- Availability of and access to digitised and curated quality data and an adapted infrastructure – creates the fuel of the EHDS for both primary and secondary use and builds the roads on which acquisition and access will run.
- Capacity and competence[42] of skilled workforce – ensures that users know how to access digitised data and how to use the system efficiently.
- Trust – creates the support among citizens, professionals and policy makers that will enable building and maintenance of the system.
- Funding and financing – is the essential underlying element in and enabler of all the four dimensions above.

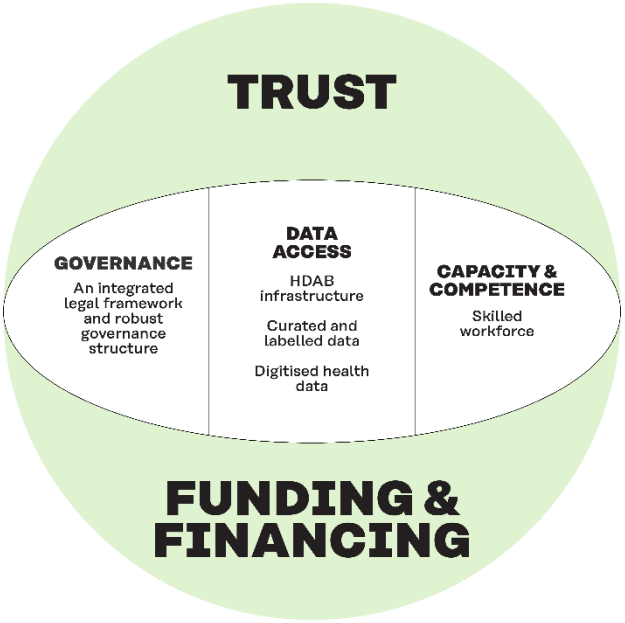

Figure 5. The five TEHDAS dimensions of sustainability.

[42] It should be noted that capacity building and competence of the work force it was not in the scope of the TEHDAS Joint Action. However, due to their importance, they will be touched upon in these sustainability recommendations.

9 Recommendations

The work of the TEHDAS Joint Action in its different work packages underpins the development of the recommendations. The contributions in view of sustainability from the TEHDAS partners and from the study visits to 12 countries taking part in the Joint Action[43] are summarised below, under the five TEHDAS sustainability dimensions.

The TEHDAS work packages have made a wealth of recommendations in their final documents. At the beginning of each section, the deliverables of the work packages are briefly listed. The recommendations below only include the main actions relevant to sustainability.

Permanent funding and governance structures at EU and national levels could provide the sufficient and consistent support that is required for a success of the EHDS2.

Politically it is imperative that the EHDS2 benefits countries equitably and that the burden of building and maintaining is equitably spread between the EU and Member States.

The recommendations set out below will require input from many stakeholders, but the lead for each recommended action is suggested to be given to the Member States or the EU (in practice the Commission), or to be led jointly.

Further, for each recommendation a timeframe is suggested: short (within 1-2 years), medium (within 3-5 years), or long (requiring 6 or more years).

9.1 Establishing a clear legal basis and robust governance framework

The TEHDAS work package Sharing data for health (WP5) analysed the main barriers of data re-use and how to overcome them[44]; produced recommendations for optimized national legislation[45]; described best practice of cross-border cooperation and data exchange, together with a template for a Memorandum of Understanding between HDABs[46]; and finally reviewed different governance options[47].

The findings on the legal landscape, on different governance options and on main barriers of data re-use built the basis for recommendations suggest that action must be taken to address the obstacles to the implementation of new EU legislation and optimising national rules regarding health data re-use. The work underlines the need for Member States to consider all these elements in their effort to develop current and future national legislation. Good national legislation would facilitate data availability and data access and build trust in its value and proper treatment among both researchers and citizens. To this end a template on a

[43] TEHDAS. Country factsheets. Mapping health data management systems through country visits: development, needs and expectations of the EHDS. TEHDAS D4.1, 28.4.2023
[44] TEHDAS. Report on secondary use of health data through European case studies. TEHDAS D5.1, 28 February 2022
[45] TEHDAS. Recommendations for European countries when planning national legislation on secondary use of health data. TEHDAS D5.2, 1 March 2023.
[46] TEHDAS. Recommendations for best practices for EU cross-border exchange. TEHDAS D5.3, 22 September 2023
[47] TEHDAS. Options for governance models for the European Health Data Space. TEHDAS D5.4, 17 January 2023

Memorandum of Understanding on cooperation in cross border secondary use of data and description of best practices in cross-border cooperation and data exchange was suggested as a support to sustainability.

During the country visits, a need for more clarity on legal and governance aspects was voiced. Several countries noted that their current legal basis for secondary use is not compatible with the EHDS as it is defined in the legislative proposal (e.g., countries that currently have a legal requirement for consent for secondary use of health data). Legal changes are being planned in several countries. However, in most cases countries are waiting for the final agreed text on the EHDS prior to making these changes to national legislation, and the result will depend on the national political landscape.

The EHDS Regulation will provide the legal basis for secondary use of data at EU level and will require each HDAB to ensure that the rights and duties it creates can be met. A key problem in the EU is that the legal bases for secondary use of health data vary across the Member States or do not exist, making cross-border collaborative research projects very difficult to execute. Once adopted, the EHDS Regulation will apply directly, and the Member States will have to take many measures to implement it fully. The EU must consider that legal changes and their implementation will take time – the EHDS will not be sustainable without investment and support to ensure that national implementation is properly done and integrated into existing healthcare systems.

The EHDS Regulation intersects with complex existing legislation, such as the GDPR and the Data Governance Act, as well as new legislation in the political process, such as the Data Act and AI Act. In order to build a sustainable governance of the EHDS, and EHDS2 in particular, it is important that time and focus is devoted to ensuring that the legal frameworks are fully understood by all parties whose work will be impacted. Thus, just as the EU and many Member States invested in targeted educational material and support to develop understanding of the GDPR, similar actions should be foreseen for EHDS, both at EU and MS level.

Setting up the EHDS governance will require establishing new bodies and, as foreseen in the EHDS proposal, a range of implementing measures. Undoubtedly, more measures will become necessary once the building of the EHDS progresses.

The new oversight bodies will need to cooperate closely with other relevant bodies, such as the European Data Protection Board. National and regional level professional and research ethics boards, patient ombudsmen and data protection authorities, as well as representatives of researchers and research industries will also need close cooperation. The EU and Member States should seek to establish rules and practices that ensure that cooperation is effective and that all such bodies are representative of all stakeholders and the citizen/patient voice can be heard. Further, their functioning needs to be transparent and understandable to citizens and stakeholders.

The learnings from the GDPR have shown that it is important to provide appropriate fora to allow Member States to learn from each other in implementing complex new legislation which heavily impact work practices but at the same time stir public opinion because of their impact on core human rights.

To foster cooperation between major European initiatives that build infrastructure elements of the EHDS2, TEHDAS organised a meeting of the "pathfinders" for the EHDS2 in September 2022. They included the HealthData@EU Pilot[48], DARWIN EU®[49], 1+ Million Genomes initiative[50] (represented by the Beyond 1 Million Genomes project[51]), and the TEHDAS Joint Action[52]. The meeting noted that all the projects work on similar or even same questions, in parallel, such as legal interoperability, EU level networking, and a sustainability plan. The participants noted that the projects would benefit from close cooperation in building of the EHDS2. In June 2023, TEHDAS also organised a meeting with the new EUCAIM project[53] of the European Cancer Imaging initiative[54]. Coordination with similar pathfinders in EHDS1 would also be necessary.

Sustainability actions recommended

No	Lead	Recommendation	Timeframe
1	MS	Assess and address potential conflicts of current practices, ethical codes and national legislation with the EHDS2, and map and address stakeholders' needs and concerns about secondary use of data.	Short
2	EU, MS jointly	Increase understanding of the legal and governance framework of the EHDS and interconnected existing and forth-coming legislation (including GDPR, Data Governance Act, Data Act, AI Act, Cybersecurity) through joint EU initiatives and support material.	Medium
3	EU	Establish an EU-funded network as a competence forum of the HDABs for a continued cooperation and sharing of good practices on the data access process. It should consult and engage actors collecting and using data.	Short
4	EU	Ensure that governance bodies, such as the EHDS Board, operate transparently and have appropriate mechanisms to consult and engage all stakeholders.	Short
5	EU	Establish close coordination between major health data sharing initiatives and projects at EU level to ensure synergies and avoid duplication of efforts as well as to support dissemination of best practices and active knowledge sharing.	Short
6	EU	Promote close dialogue and alignment across EHDS1 and EHDS2 aspects, facilitating the translation of knowledge between both "sub-spaces" to maximise the transfer and applicability of the findings in the day-to-day caregiving practice, decision making and regulation.	Medium
7	EU	Produce guidance for and set up effective cooperation of governance bodies of the EHDS and relevant oversight bodies, such as EDPB and EDPS, as well as for similar bodies at national level.	Short

[48] https://ehds2pilot.eu/
[49] https://darwin-eu.org/
[50] https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
[51] https://b1mg-project.eu/. The work of B1MG will be continued in the Genomic Data Infrastructure project https://gdi.onemilliongenomes.eu/
[52] https://tehdas.eu/
[53] https://cancerimage.eu/
[54] https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging

No	Lead	Recommendation	Timeframe
8	EU, MS jointly	Create guidelines for harmonisation of interpretation of key requirements in relation to relevant and interlinked legislations across the Member States.	Medium

9.2 Ensuring access to quality data

The TEHDAS Work Package "Excellence in data quality" (WP6) developed the EHDS2 Data Quality Framework[55] and recommended means to ensure data quality. The Work Package named "Connecting the dots" (WP7) proposed options for the EHDS architecture and services that could be provided in the EHDS2[56], [57]. Relevant in the context of this document in particular, the services include the financial service that would facilitate cross-border fee payments.

Each Member State should assess the availability of health data held by both public and private sector bodies to be made available through the HDAB(s) on its territory. It should assess the current state of digitisation and allocate adequate funds from EU or national budgets to ensure that new health data are generated in a way that allows them to be used in the EHDS as well as to assess to what extent historic data should be converted.

The EHDS Regulation will require HDABs, among other things, to catalogue data sets, to ensure that the data sets follow common standards and to ensure the quality and utility of the data set. All these elements will entail implementation and maintenance costs in establishing and data management and data quality management procedures. It is likely that the national implementation will seek to improve the quality of data. These requirements implemented in practice at national level may demand significant resources falling on data holders.

Where data holders have a high level of maturity with data quality management procedures already in place, the cost incurred in data preparation may be marginal, but many data holders will need a high initial investment to meet the data quality standards that are likely to be set.

TEHDAS developed an extensive Data Quality Framework (DQF), which shifts the focus to continuous improvement and promotion of data quality. The document underlines that collection, use and storage of healthcare data is organised differently across Member States. Therefore, it is difficult to compare the situation between the Member States. Secondly, data quality is multidimensional. Quality is relative to the need of the user and hence a particular data set may meet the quality requirements of one user, but not of another. Generic metrics for quality measurements can be developed but their interpretation should be case-specific.

[55] TEHDAS. Recommendations on a Data Quality Framework for the European Health Data Space for secondary use. TEHDAS D6.3, 26 September 2023
[56] TEHDAS. Options for the minimum set of services for secondary use of health data in the EHDS. TEHDAS D7.1, 5 April 2022
[57] TEHDAS. Options for the services and services architecture and infrastructure for secondary use of data in the EHDS. TEHDAS D7.2, 4 July 2023.

The EHDS DQF should be able to accommodate all relevant institutions in Member States. This premise of inclusiveness underlines that every Member State should be able to take part in the EHDS, also the levels of data quality and auditing should balance this premise.

Setting nationally the ambition level of data quality will have a major impact on costs of the EHD2 in each Member States but also determine the benefits.

The governance of data quality has been addressed extensively (see D6.1) by TEHDAS. Tasks of data holders include: 1) achieving the highest possible level of maturity in data quality; 2) implementation of layers of interoperability, ideally through international semantic standards and data models; 3) implement an international meta-data standard; 4) HealthData@EU data quality and utility label; 5) pre-process datasets to get them linked; and 6) minimise risks using privacy enhancement technologies (PETs). Health data access bodies, on their part,) will need to deliver the tasks defined in Article 37, and further, secure processing environments (SPE) require managing several tasks (see D7.2).

In the in-depth analysis of potential standards for HealthData@EU, TEHDAS concluded that data discoverability would benefit from the combined use of generic and domain-specific standards. For example, the mapping of medical concepts from taxonomies and controlled vocabularies to SNOMED CT needs to continue. Standards adopted will have an important cost impact, which also needs to be looked at.

Before the EHDS can be developed for primary or secondary use, health data collected through each patient encounter or using a medical device must be digital. While most Member States are using some form of EHR these are far from standardised across different care providers within countries.

Recording the data is significant time cost for healthcare providers and the current systems are not always fit for smooth processes. The burden could be reduced by creating user-friendly, well-designed interoperable systems. The funding needs for additional work in digitalisation, standardisation and semantic harmonisation of health data in hospital and primary care settings need to be addressed. This includes the time spent by healthcare professionals recording and validating the electronic health records and resources used by data holders to implement data quality assurance procedures.

Data requests may entail data linkage, data harmonisation, and data transformation processes before delivery. Data holders should be obligated to publish their data preparation procedures, metadata about their collections, including information on data provenance, relevance and coverage of the data collection and ensure the highest possible degree of transparency. This as well as the primary collection of data will need financial and other incentives.

The initiatives should focus on continuous improvement, encouraging good practice, design, development and implementation of toolkits for quality assessment and allocate resources to support data quality-focused work.

While most MS have some form of health data hub, i.e., an institution that gathers and curates data from multiple data holders, these are not built in a uniform manner. In some countries with regional data access bodies these are not yet co-ordinated.

TEHDAS has defined many services to be provided within the EHDS2 and analysed options for setting them up (see D7.2). In general, as in the case of quality, the extend and level of services will have an important impact on costs.

As a part of the services to be provided within the EU and national implementation of the EHDS2 according to Article 42, Financial Services deserve attention in the context of sustainability. The financial services include all software elements to manage the financial transactions associated to the EHDS2 fees and operating costs. Most likely there will be user charges for accessing and using the data, thus requiring software elements to manage cross-border billing and invoicing between HDABs. TEHDAS recommends a distributed model where all nodes provide the financial services and orchestrate the operation across them. In this scenario, fee payment is done to the HDAB which the data user accessed and the fee is redistributed to other HDABs.

Sustainability actions recommended

No	Lead	Recommendation	Timeframe
1	MS	Conduct a detailed national assessment of available health data held by key public and private sector data holders, allocate budgets to support public sector data holders making data available to HDABs.	Short
2	MS	Identify and allocate capital funds to create HDABs and provide the foreseen services, building where possible on existing national level structures and accessing EU level funds from EU4Health, Digital Europe and other programmes.	Short
3	MS	Clarify the internal organisation of the HDAB or HDABs, if several, and develop the relationship and communication channels between them and the data holders, as data holders will have an additional burden not necessary a part of their core business.	Short
4	MS	Develop a clear plan to guarantee data holder enrolment with an incentive programme – financial and other – to help them provide high-quality data to HDABs, implement data quality management procedures, use agreed semantic standards and adjust to common data models, which are likely to be agreed upon to get the full benefits of the secondary use of health data.	Medium
5	MS	Build initiatives that focus on continuous improvement, encouraging good practice, design, development and implementation of toolkits for quality assessment and allocate resources to support data quality-focused work.	Medium
6	EU	Foster the work on the developing and deployment of SNOMED CT and other recommended standards as well as analyse of the costs of their implementation and maintenance and how these costs should be financed.	Long
7	MS	Analyse at which level services should be provided within the national implementation of the EHDS2, taking into account the services provided by the EU.	Short

No	Lead	Recommendation	Timeframe
8	MS	Create and develop new roles and processes for the foreseen services (data discovery, data access requests processing or coordination of SPEs among others) to deliver access to quality data in the long-term.	Medium
9	EU, MS jointly	Reduce administrative burden at all levels - EU, national, regional and data holders - by creating systems that facilitate work and avoid duplication.	Medium

9.3 Building capacity and competence[58]

Every aspect of the EHDS will require the deployment of skilled human resources, whether that is in developing infrastructure, embedding it in healthcare system operations, providing services to potential secondary users of health data or ensuring the proper governance of the operation of HDABs and contributing the governance of the EHDS at European level. Staff costs will arise predominantly in the public sector but also on private sector entities.

TEHDAS did not work directly on capacity building but the need to guarantee the skills and knowledge of data users of the data sprang up throughout the work. The capacity building dimension must be included in the sustainability recommendations because all services envisioned in the EHDS require a capable workforce to establish and maintain them. This function was termed Support & Training Services. The TEHDAS report[59] noted the potential to provide support at EU and national level focussed on the phases identified in the TEHDAS Users' Journey: interacting to discover the required health data; submitting the permit application to access data in the proper manner; using the secure processing environment (SPE); and managing the results of the analysis.

As researchers in academia, industry and in public sector are encouraged to seek access to data through the HDABs in their countries and to the data held in other Member States through the HealthData@EU, they must know how the system operates, what data are available and to trust in the quality of the data.

Capacity and training availability and needs were explored also during the country visits. Many stakeholders noted significant human resource needs, in particular for IT and legal expertise. Specific human resource needs follow the three-stage model: a) skilled staff for maintenance and operation of data collections, b) administrative and scientific staff for access applications and c) data analysts, and data scientists.

Staff capacity and competence will be one of the most demanding elements of the EHDS. It is likely that only a limited number of new posts will be created, and training and further development costs of existing staff must be accounted for at national, regional and local levels. Furthermore, such costs will be on-going and, when the use of the EHDS2 increases, they may rise.

[58] Capacity building and competence was not in the scope of the TEHDAS Joint Action. However, due to their importance, they are discussed briefly here.
[59] TEHDAS. Options for the minimum set of services for secondary use of health data in the EHDS. TEHDAS D7.1, 5 April 2022

Sustainability actions recommended

No	Lead	Recommendation	Timeframe
1	MS	Identify education and training needs and allocate budgets to ensure HDABs can deliver high-quality services, considering readiness for various data processing needs.	Short
2	EU	Set-up strong and highly skilled support teams at EU level to ensure effective operations to prevent HDABs failing in their responsibilities of providing access to data for secondary use.	Short
3	EU, MS jointly	Develop a wide range of dissemination and educational materials on the EHDS as well as teaching activities to help build capacity and confidence. Coordinated training should be provided at EU level, considering differences between countries and their needs.	Medium
4	MS	Increase understanding of implications of the EHDS, provide training to both frontline health professionals and end-users of health data. Also the curricula of health professionals need to include education on digital health, digital health literacy and human-centric and trustworthy AI.	Medium
5	MS	Put in place staff development initiatives for the skilled profiles needed (e.g., data analysts) and incentives for retention of skilled staff in collaboration with other EU digital skills initiatives.	Long

9.4 Fostering trust among citizens, professionals, and policy makers

The TEHDAS work package Citizens (WP8) studied citizens perceptions of sharing of health data[60], and developed recommendations for data altruism practices[61]. The results of the TEHDAS Healthy Data consultation carried out in Belgium, France and UK suggested that the several important factors should be considered to create and maintain support among citizens, professionals, researchers, industry and policy makers.

The EHDS represents a significant change in the health data economy. It has the potential of making data more easily accessible to data subjects for their own use and to further their ability to take such data to healthcare providers of their choice. In terms of secondary use, its objective is to radically increase the re-use of data that are routinely collected in patient care, as well as data that are generated using medical devices and wellness apps, as well as in clinical trials.

Although in general citizens support the secondary use of health data, it is necessary to encourage citizens' involvement in the EHDS. The results of the Healthy Data consultation showed that citizens' support is conditional on effective balancing the benefits citizens support and the risks they identify as well as ensuring citizens have an active role in decisions on reuse. Partly because of the risks people perceive in secondary use and the personal and

[60] TEHDAS. Qualitative study to assess citizens' perception of sharing health data for secondary use and recommendations on how to engage citizens in the EHDS. TEHDAS D8.1, 31 March 2023
[61] TEHDAS. Report on lessons learned to be applied and recommendations for data altruism practices, TEHDAS D8.2 (to be published)

powerful nature of health data, citizens prefer a certain degree of individual choice regarding secondary use, for instance by means of consent or active engagement.

Citizens require a regulatory framework for secondary use to have appropriate governance structures but also to respect for ethical values as identified by citizens. Broadly the primary ethical values citizens outlined were use of data for the common good, ensuring social inclusion in data use and citizen autonomy and control. Citizens' and all other stakeholders' understanding of the benefits of the secondary use of health data is important to ensure buy in.

An essential element for building trust is facilitation of the control of citizens and patients over their data, as well as transparency on where, how and to whom health data are shared, and what the advantages of data sharing are.

This demands communication and advocacy by national authorities and trusted parties. The costs of communication programmes would not be very large in the context of all the costs but its contribution to the sustainability of the EHDS would be significant. EU level initiatives on advocacy for the EHDS can support national initiatives.

The role of social media is important in engaging with people, but also the specifics of social media as not everyone engages in social media in the same way. There is a risk that people with lower level of digital literacy are left behind and, in this way, not engaged.

The safeguards included in the EHDS proposal aim at fostering trust and reference is made to the importance of best practice sharing between Member States. Actions to foster trust begin close to the potential secondary user of health data.

Sustainability actions recommended

No	Lead	Recommendation	Timeframe
1	MS, EU jointly	Engage all the stakeholders (citizens, professionals as well as policy makers) at all levels and throughout the process of implementation of the EHDS to ensure understanding and support to the secondary use of health data.	Short
2	MS	Develop strong and effective citizen communication around the secondary use of health data, including use cases demonstrating the added value for all stakeholder groups.	Short
3	EU	Support exchange of best practices regarding effective communication and awareness raising strategies that lead to increased understanding and acceptance.	Medium
4	MS	Prepare for measures and communication in situations where problems have occurred in the use of health data despite all safeguards and precautions.	Short
5	EU	Study the role and uses of social media, with the aim to reach all citizens, to visualise uses and benefits of sharing health data in the EHDS2.	Medium
6	EU, MS jointly	Implement stringent tools to safeguard the data collected and to prevent any misuse, and strengthen cyber security.	Short

No	Lead	Recommendation	Timeframe
7	MS	Provide individuals means to understand where and how their data is used and provide options for individuals to manage better their health data.	Long

9.5 Ensuring adequate funding and financing

The TEHDAS work has shown that estimating the resources and funding needed to set up the system of secondary use of health data within the European Health Data Space is currently difficult. The reasons are mainly: 1) The cost impact spreads widely in the Data Lifecycle and the service-mix provided. 2) Few national examples exist, and they have not yet reached the cruising altitude.

European Commission's work on the impact assessment provided details of estimates for costs and benefits in Annex 5[62]. In the impact assessment, the Commission has estimated the costs and benefits above the baseline as required by the EU decisions (eg. baseline vs. Option 2+). Member States will be concerned also by the total cost, including the national implementation. It is unlikely that better estimates would be possible without new research.

Predictable, fair and sustainable EU funding is a prerequisite for the successful implementation of the EHDS2. Given that the objective of the EHDS2 is to create a system that allows data to be accessed within and between countries, it will be important to share equitably the burden between the EU and the Member States.

The maturity of national systems of secondary use of health data and in particular HDABs to join the network varies. The EU funding needs to consider the very different situations of the secondary use of data in Member States, as seen during the TEHDAS country visits. It is important to create incentives and opportunities for progress in the use of health data regardless of the starting position.

The funding of cross-border projects needs to be thoroughly discussed. Agreeing on the principles of cost sharing between the EU and Member States is important as the funding needs to come through both the EU budget and the national sources. While the European coordination actions need clearly to be funded from the EU sources, there are needs in Member States to invest and maintain their national data collection and access systems which feed the European exchange. The current Direct Grants in the EU4Health programme for setting up Health Data Access Bodies has been a helpful step to that direction.

The increase of the EU budget for health, as welcome as it is, creates resource problems at national level when all EU projects need national co-funding as required by the programme regulations. With more and bigger projects, the national contribution increases. Many Member States lack mechanisms for national funding. Even 40% own contribution is considered high. Consequently, many Member States, hesitate to join as they are not willing to find the national contribution. This difficulty applies in particular to the EU-level coordination component of projects. Therefore, the EU should seek to use mechanisms that require less

[62] https://health.ec.europa.eu/document/download/2a359bf7-d0bc-43e4-b87a-45e709273cfc_en?filename=ehealth_ehds_2022ia_2_en.pdf

self-financing when EU-level coordination is involved, such as Coordination and Support Actions (CSAs) or calls for tender.

Traditionally EU projects are financed under time-limited, short-term contracts on ad-hoc basis. The current project-based funding brings many problems, including a potential overlap and inefficient use of resources. At EU level, only the two agency-based specific data sharing mechanisms studied[63] by TEHDAS (TESSy and DARWIN) seem to have escaped the problem of repeated project funding.

The EHDS2 Regulation will set up a permanent data sharing across the EU countries, which needs both stable governance structures, technical infrastructures and funding. Once the EHDS2 has been established, running the technical elements of the system, such as HealthData@EU, will become a routine task. Such technical tasks are in Member States usually allocated to technical agencies; ECDC and EMA are such agencies at EU level carrying out day-to-day operations within their mandates. According to the EHDS proposal, the central platform would be an obligation of the Commission on a permanent basis. This is the same construct as in MyHealth@EU. The national infrastructures remain responsibility of Member States.

The Commission's impact assessment discusses explicitly and rejects (page 65-66) the possibility of a new agency or expanding the mandate of ECDC or EMA. However, this assessment was made in the broader policy context and before practical experience of the cross-border secondary use of health data. The analysis should be repeated in a new study, when the specifications of EHDS tasks at EU level have been agreed upon and the first experiences of the cross-border use of health data have flown in. A stable structure[64] at EU level can be implemented in different ways.

Services to be provided within the EHDS at EU and national levels will have a major influence on the costs. While the service catalogue still needs to be agreed upon, it is unlikely that any major component, such as the secure processing environment, could be left out. However, the level and quality of service can be adjusted. Setting up EU interoperability and making good quality data accessible will entail costs to both data holders and data access bodies. However, the European interoperability will also foster and secure national efforts and bring saving on a longer run, if supplemented by co-creation of practices and tools.

The EHDS is heavily dependent on co-operation between Member States. Creating the EHDS2 could be seen as a co-creation process where Member States develop jointly common practices and tools in open source that can be re-used and adapted in national and subnational nodes of EHDS2.

Building a European data access and sharing system has an impact on the national data collection, access mechanism and use, their development and consequently on the costs to public stakeholders. To be ready to establish the financing needs, assessment of costs should be undertaken at national level in the MS and their results pooled at EU level to build up a better picture of budgetary requirements of building and sustaining EHDS2.

---

[63] TEHDAS. Preliminary study on funding sources and costs of secondary use of health data in the EU. Milestone 4.3, 1 April 2022.

[64] Martins H. EU health data centre and a common data strategy for public health. European Parliamentary Research Service (STOA) PE 690.009, September 2021

The national roadmap should not only include the costs of data access stage but also an assessment of resources needed in the data collection to data use stages (the Data Economy Three Stage Model). The roadmap should look at national funding and, where appropriate, by accessing support from EU financing instruments. In addition to funding the system, also the benefits should be looked at. It would be crucial to create case-specific cost estimates both at national level and share them with other Member States.

The HealthData@EU Pilot[65] will make much clearer how EHDS2 is to be developed and implemented and the budgetary needs will become clearer. It is important that the Member States at this stage of developing the EU system either participate directly in or at least the use work carried out in TEHDAS and the Pilot as basis for conducting national level assessments on readiness and maturity. This enables them to develop informed and actionable plans, together with viable financing.

A more intensive attention is needed to bring the benefits of the EHDS2, which necessitates joint actions between public and private actors. This could be done through a European partnership[66] or another appropriate mechanism for supporting the important policy initiative.

In general, countries and project partners have expressed a need for more and sustainable funding for the EHDS, both to support human resources and to develop the technical infrastructure. This was a common concern across many stakeholders during all country visits[67]. A hybrid model was advocated, which would include EU level funding in addition to national funding resources. The TEHDAS Policy Forum[68], which discussed the implementation and financial sustainability of the EHDS from national policymakers' perspective, expressed concerns of insufficient funding, especially in the long-term, and potential costs for data users, such as researchers and healthcare providers.

Sustainability actions recommended

No	Lead	Recommendation	Timeframe
1	MS	Create a national road map to implement the EHDS2, taking into account the experience from other countries and using the support from EU pathfinder projects, such as TEHDAS, HealthData@EU Pilot, and EUCaim.	Short
2	MS	Develop specific, detailed cost estimates for defined services of EHDS2 to establish where costs and benefits will accrue.	Medium
3	MS	Acknowledge and address the funding needs for additional work in digitalisation, standardisation and semantic harmonisation of health data in hospital and primary care settings.	Medium
4	EU, MS jointly	Agree on principles of cost sharing related to cross-border use of health data in order to arrive at an equitable division of the financing burden of EHDS2.	Medium

[65] https://ehds2pilot.eu/
[66] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe_en
[67] TEHDAS. Country factsheets. Mapping health data management systems through country visits: development, needs and expectations of the EHDS. TEHDAS D4.1, 28.4.2023
[68] TEHDAS convenes European ministries to discuss implementation of the European health data space. TEHDAS news report, 12.12.2022.

No	Lead	Recommendation	Timeframe
5	MS	Engage in pilots and best practice exchanges with those MS with an experience to HDAB execution to model budgetary needs and operational processes.	Short
6	EU	Develop open-source tools for EHDS2, funded by research and innovation programmes, that can serve as the basis of common co-created solutions and would otherwise need to be set up by the Member States separately.	Short
7	EU	Use more fully funded financing instruments, such as coordination and support actions (CSAs), to promote cooperation of Member States on EHDS2.	Medium
8	EU	Consider supporting the EHDS policies with a European partnership initiative, ensuring the linkages between various actions and bringing together actors from private and public sectors, to promote co-creation and ensure long-term commitment the aims of the EHDS.	Medium
9	EU	Consider options for developing the permanent structure maintaining the minimum common services of the EHDS2, to ensure their long-term functioning.	Long