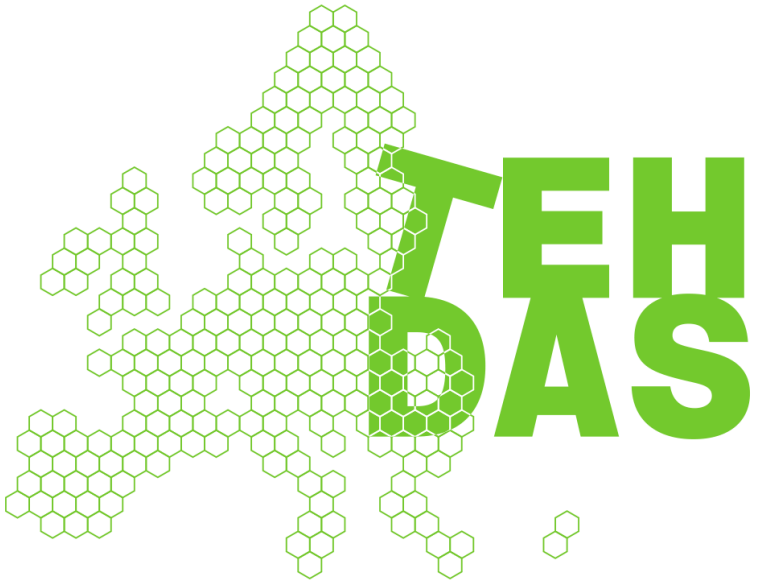

Towards European Health Data Space

Milestone 4.3

Preliminary study on funding sources and costs of secondary use of health data in the EU

1 April 2022

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1 Executive summary

In the TEHDAS Joint Action's vision, European citizens, communities and companies will benefit from secure and seamless access to health data regardless of where it is stored. This will require a system that has a sound legal, organisational and technical basis. However, the European Health Data Space will also need sustainable resource and funding arrangements both at EU and at national (or regional) levels. A sustainability plan is a prerequisite of the successful launch and maintenance of the EHDS.

This document aims at supporting discussion on the economic aspects and sustainable funding of the EHDS. It provides an insight into funding mechanisms at EU and national level and analyses the funding arrangements of selected existing health data sharing mechanisms.

To study sustainability elements of the EHDS, an analytical framework is needed. The TEHDAS user journey model and the catalogue of relevant services is complemented with earlier and later stages in the economy of the secondary use of health data.

In the analytical framework, the first stage is data collection that is carried out for the primary purpose of the data use, which does not necessarily consider its secondary use. The second stage is the data access management as defined in the user journey. The last stage in the data economy is the actual analysis for research or other secondary purposes. In the framework, it is necessary to discuss possible sources for funding and various types of costs.

The data economy has many policy-related aspects that are not simply related to operational costs of the EHDS. However, they will be relevant in the policy making process.

The document gives a brief overview of the EU's funding instruments relevant to the secondary use in the periods of 2014-2020 and 2021-2027. They may be used for funding of action on health data collection, access, and use. Two calls scheduled for 2022 under the EU4Health programme are of immediate interest as they will specifically address the infrastructure and governance of the European Health Data Space as regards the primary and secondary use of data (each have a budget of €30 million).

Six existing EU health data sharing mechanisms are described in more detail. They illustrate issues related to efforts to fund setting up and maintaining health data sharing mechanisms.

The European level data sharing cannot work without functioning systems in Member States for data collection and access. It is important that Member States also develop their capacity in the third stage, to benefit from the use of data. Examples from Finland, the Netherlands, and Denmark describe aspects of national health data economy. Further countries, including Belgium and Latvia, are in process of setting up their national structures and considering also the costs involved.

Building a European data access and sharing system will have an impact on the national data collection and access mechanisms, leading to a need to develop national systems. It will raise questions of funding the costs to the governments of developing their national systems as well as joining the European data exchange. The cost sharing principles between the EU and Member States and funding through the EU and national budgets need to be thoroughly discussed.

2 Context

In the TEHDAS Joint Action's vision, European citizens, communities and companies will in the future benefit from secure and seamless access to health data regardless of where it is stored. This will require a system that has a sound legal, organisational and technical basis. The TEHDAS Joint Action[1] considers that the sustainability is a prerequisite of the successful launch and maintenance of the EHDS.

The EU health legislation, in particular the future proposal for the European Health Data Space, will establish the legal basis for the data sharing framework. However, the EHDS will need also sustainable organisational and resource arrangements both at EU and at national (or regional) levels. Of these arrangements, funding is one of the most important. Sustainable funding will need a viable economic model both at EU and national levels, which can be maintained over years.

Through country visits and its policy forum, TEHDAS explores the views of Member States on the economic sustainability of the EHDS and will suggest concrete ways to integrate the results into the future EHDS.

The results of the TEHDAS work on sustainability will be published in early 2023 as a Sustainability Plan[2], which will present a pragmatic roadmap providing recommendations on the future implementation of EHDS. The Plan will include inputs from the country visits and integrate results of all the work packages of the TEHDAS Joint Action. It will also comment on the funding and resource needed for the European Health Data Space.

This exploratory document (M4.3) maps existing financing options that could be used for funding of the EHDS at EU level and discusses how they could be linked to national funding mechanisms. This document aims at

- supporting discussion on the economic viability and sustainable funding of the EHDS
- providing insight into funding mechanisms at EU and national level; and
- analysing the financing of selected existing health data access and sharing mechanisms as examples.

The current document seeks to present a framework on how the economic sustainability could be analysed but does not provide the answers yet. The questions on the economics of the secondary use of health data cover data collection, access as well as sharing mechanisms.

1. What framework should we use for the analysis of the economic sustainability including data collection, data access and data use (Chapter 3)?
2. Which sources of funding exist at EU level for implementing actions required by the successful establishment and European Health Data Space during 2021-2027 (Chapter 4)?
3. How is the national funding of data access for secondary use organised and what are its links to the EU-level funding, and which are their economic models (Chapter 5)?
4. How has funding been organised for some current data exchange mechanisms, which are relevant as examples for the secondary use of health data (Chapter 6)?
5. Discussion on key aspects related to funding at EU and national level for arranging the secondary use of health data (Chapter 7).

[1] Work is carried out in Work Package 4 on outreach, engagement and sustainability (WP4)
[2] A TEHDAS deliverable with a document code D4.3

Questions be studied in designing the Sustainability Plan will go beyond the question of funding and available sources at EU and national levels. On the income side, the economic model may include user charges. On the cost side, the economic model includes various types of costs, such as the initial investment, maintenance, infrastructure, and staff. Further, many non-financial resources are necessary for implementing secondary use cases, such as human resources, skills and knowledge. The maturity of the countries in the secondary use of health data varies in the European Union[3].

The costs of primary use (often referred to as EHDS1) and the secondary use (EHDS2) of health data are clearly interlinked. The TEHDAS Joint Action focuses on the cross-border secondary use of health data but the European Health Data Space will cover also the primary cross-border use of health data, among other issues. This document concentrates on the secondary use but acknowledges the links between the primary and secondary use.

The resources needed for the operation of the EHDS2 at EU level are heavily dependent on the level[4] and type[5] of services provided within it. At national level, the maturity of the national system influences the national investment needed. This document does not seek to quantify the resources needed as this requires the decisions on those services first.

The value created by the secondary use of health data is one of the broadest questions. This could be approached by studying examples from other fields, e.g., transport or banking. This question is not included in the tasks of the TEHDAS Joint action.

Important aspects related to sustainability are being or will be addressed in other TEHDAS documents, such as

- legal sustainability in the work on sharing data for health (Work Package 5), and
- technical sustainability in the work on excellence in data quality and connecting the dots (Work Packages 6 and 7).

While this document describes possible sources of funding of the European Health Data Space, it does not make any recommendations.

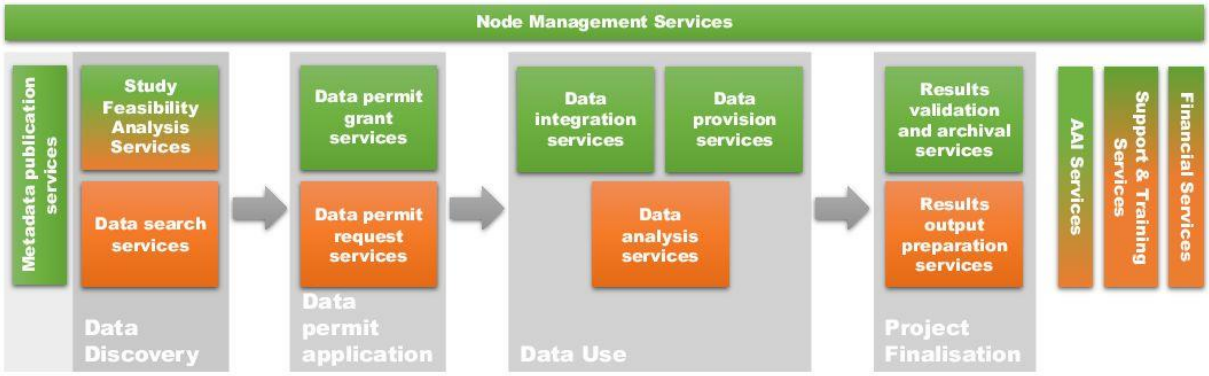
[3] Survey results: National health data infrastructure and governance, OECD Health Working Papers
[4] See the discussion on costs of quality in Identifying those data quality features that could be legally bound and providing advice to the European Commission, TEHDAS M6.1, 11 November 2021
[5] The WP7 document on the steps of the user journey: Catalogue of EHDS services for secondary use of health data, TEHDAS M7.5, 9 December 2021.

3 Analytical framework for sustainability

This section helps the reader to get an idea how to analyse the sustainability challenge.

The EHDS2 data user's journey and the related services provided have been extensively described in another TEHDAS document[6]. That can be used as a starting point of analysing the costs of setting up and running services provided by the EHDS2 nodes. Those services are essential in access to data and its initial use.

Figure 1. The EHDS2 users' journey presented as the EHDS2 node management services



For deciding on the framework of the sustainability elements to be included in the analysis, it is necessary to complete the users' journey model with the earlier and later stages in the data economy. Including all stages of the data economy fully into the analysis would, however, enlarge the scope of the analysis and be unfeasible. Thus, the limitation of the analytical framework for economic costs and benefits is necessary.

Figure 2. Three stages in the use of data in the data economy

The first stage in the data economy 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 TEHDAS context. This can include structuring the data and increasing its quality or developing the technical infrastructure.

All elements in the second stage, as detailed in the users' journey and the related services, are relevant for the sustainability analysis.

The last stage in the data economy is the use of data, in the actual analysis for research or other secondary purposes. The last stage, the funding of research or costs of the data analysis in public administration or within companies, also falls largely outside the scope of the TEHDAS Joint Action and consequently this document. However, the EHDS may offer services which facilitate the data processing which traditionally were within the remit of the research process itself.

[6] TEHDAS. Options for the minimum set of services for secondary use of health data in the EHDS. TEHDAS D7.1 2022-03-29.

The second relevant aspect for the limitation of the analysis relates to national and cross-border use of data. While the EU proposal on the EHDS will deal with the cross-border aspects of data use, such use is tightly linked to the national data availability. The EU will seek to incentivise and support developing the national data collection, access and sharing as it is also a prerequisite for the cross-border use. The national costs cannot therefore be overlooked.

For the analysis, sources of funding and income are relevant, such as project funding from the EU and other public bodies, continuous budget funding (EU, national government), service and user fees, and others, including joint investments with private actors.

Many types of costs need to be looked at: initial investments in the infrastructure, maintenance of operations, but also its further development, as well as administrative costs (coordination at national and EU levels). Investing in developing skills and knowledge of the workforce, education and training, is a considerable cost and a prerequisite for sustainability but not analysed in detail in TEHDAS.

In this document the following concepts are mainly used:

- The economic model is the description of the overall sources of income and use of economic resources and the benefits of action.
- Funding refers to the support provided by the public sector, such a grant by the EU or the budget allocation by a national government. User and service fees may be included in the concept.
- Financing is a wider concept and may include other types of economic revenue. It often refers to money that is expected to be paid back, such as an investment loan.
- The term business model puts an emphasis on the business aspect of the operation, which in this context is not relevant.

3.1 On the economy of the secondary use of health data

The data economy has various aspects that are not directly related to operational costs of the EHDS, but which will be relevant in the policy making process. In this section we start describing some of the issues that are relevant without providing answers yet.

The benefits of the secondary use of health data are often difficult to measure but they need to be made visible in the public discussion. While the benefits may be obscure, the costs immediately visible. Therefore, it is important to consider concerns expressed by healthcare and local, regional, and national policy makers.

When considering costs and benefits in connection to sharing of health data for secondary purpose, healthcare is asked to perform tasks which will not always directly benefit the data holders. They may be asked to perform activities for which they have not designed their infrastructures and capacities. Moreover, they are expected to provide data of high quality, possibly even better than need for primary purpose.

Geographical and global aspects of data sharing for secondary purposes are also worth considering. Repurposing of healthcare data can bring new and better products and procedures to the healthcare market if there are enterprises that are capable to grab the opportunity and develop new or enhanced products. Will the effort associated with making data available be used primarily by European or global industries? This may be particularly topical if the EU industry is given no preferential access.

Local healthcare providers and authorities will understand the economy with data if they see such companies in their regions or countries. The data holders and subjects in healthcare typically think first locally, regionally, or nationally due to the nature of healthcare services.

Furthermore, the current political attention focuses more on local and EU production than purchasing articles or services from distant sources. This may strengthen the relation of data location and local research to the local industry.

4 Overview of the EU's funding instruments

This chapter gives an overview of the funding mechanisms and their possibilities i.e., funding programmes in the periods of 2014-2020 and 2021-2027.

The EU has many funding and financing mechanisms[7], including the Recovery and Resilience Facility, which may be used on health data collection, access, and use. As the focus is on the secondary use, the document looks at the most relevant possibilities.

4.1 Past Multi-annual Financial Framework for 2014-2020

While the multi-annual financial framework (MFF) 2014-2020 has ended, many projects still run using the funding from it. This section will outline some of the main EU funding programme during that period. Projects financed during the 2014-2020 period can provide important examples for the potential financing of a future EHDS. Further analysis of the problems and issues will be provided in the tables below in chapter 6.

4.1.1 Health Programme 2014-2020

The third EU Health Programme 2014-2020 was adopted in March 2014, as the European Commission's main instrument to fund the EU's health strategy. The two previous Health Programmes ran from 2003-2007 and 2008-2013. Its objectives were to help EU countries respond to economic and demographic challenges affecting their health systems, and to help keep European citizens healthy for longer.

The specific policy objectives of the EU Health Programme are:
- Contributing to innovative, efficient and sustainable health systems
- Increasing access to better and safer healthcare for EU citizens
- Promoting good health and preventing diseases to improve citizens' health
- Protecting citizens from cross-border health threats.

The third Health Programme had a budget of €449.4 million, and projects funded by the third EU Health Programme continue after 2020. The final evaluation of the third EU Health Programme should be published at the end of 2021. However, by the end of 2019 the programme had funded over 350 actions involving 7322 organisations across Europe.

4.1.2 Horizon 2020

Horizon 2020 was the EU's funding programme for research and innovation for the period 2014-2020 and was replaced by Horizon Europe. The Horizon 2020 budget was €77 billion, making it the largest EU research and innovation programme at the time.

Horizon 2020 was the financial instrument implementing the EU's Innovation Union, with the overall aim of ensuring the EU's global competitiveness. Its thematic sections included: excellent science, leadership in enabling and industrial technologies, innovation in SMEs, access to risk finance, societal challenges, and spreading excellence and widening participation. The first societal challenges identified within Horizon 2020 was 'Health, demographic challenge and well-being'.

[7] The European Commission describes relevant financing instruments in the EU4Health 2021-2027 – a vision for a healthier European Union.

Horizon 2020 provided funding for research and innovation projects based on these thematic sections, with the aim of bridging the gap between research and the market. In terms of the secondary use of data, examples of Horizon-funded projects include:

- PHIRI (Population Health Information Research Infrastructure)
- InfAct (Joint Action on Health Information)
- ImpleMentAll (implementation of eHealth interventions)
- EOSC-Life (collaborative space for biological and medical research)
- EJP-RD (Joint Programme on Rare Diseases, creating a rare diseases research ecosystem)
- HealthyCloud (delivering a strategic agenda for the European Health Research and Innovation Cloud)
- Do IT (big data health research)
- EHDEN (European Health Data Evidence Network).

4.1.3 Connecting Europe Facility (CEF)

The Connecting Europe Facility (CEF) is an EU funding instrument which aims to promote growth, jobs and competitiveness through targeted infrastructure investment at EU level, including in digital services and telecom. The CEF focusses on investing in projects that strengthen the European Single Market, including connectivity infrastructures and interoperable digital services.

The CEF budget for the period 2014-2020 was €30.4 billion. As of 2019, the CEF had funded almost 1400 actions. The CEF was renewed for the period 2021-2027, as will be outlined below.

4.1.4 European Structural and Investment Funds (ESIF)

The EU's structural funds are jointly managed by the European Commission and EU Member States through partnership agreements. They channel funds with the aim of investing in job creation and a sustainable and healthy European economy and environment.

The ESIF had five focus areas:

- Research and innovation
- Digital technologies
- Supporting the low-carbon economy
- Sustainable management of natural resources
- Small businesses.

There are five European structural and investment funds: European regional development fund (ERDF), European social fund (ESF), Cohesion fund (CF), European agricultural fund for rural development (EAFRD) and the European maritime and fisheries fund (EMFF).

4.2 Current Multi-annual Financial Framework for 2021-2027

4.2.1 EU4Health

EU4Health is the fourth and largest EU health programme financially, providing €5.3billion for projects that take place between 2021 and 2027. This programme was the EU's response to the COVID19 health crisis, which affected the health systems and many sectors of the European economy and revealed how interconnected and interdependent the European, but also global, health, research and economy are. The €5.3 billion budget is directed to European countries, NGOs and health organisations.

It aims to financially support projects that will boost the EU's preparedness for major cross border health threats by creating:

- Reserves of medical supplies for crises
- A reserve of healthcare staff and experts that can be mobilised to respond to crises across the EU
- Increased surveillance of health threats.

It also aims to strengthen health systems so that they can face epidemics as well as long-term challenges by stimulating:

- Disease prevention and health promotion in an ageing population
- Digital transformation of health systems
- Access to health care for vulnerable groups.

Finally, it supports projects that:

- Make medicines and medical devices available and affordable
- Advocate the prudent and efficient use of antimicrobials
- Promote medical and pharmaceutical innovation and greener manufacturing.

Although the EU4Health programme is focused on EU's preparedness to a future health crisis and cross-border communication and surveillance of health threats, it also funds research projects on cancer, antimicrobial-resistance and vaccination. Finally, it also aims to expand successful initiatives, such as the European Reference Network for rare diseases.

It is important to highlight that the Commission is planning to collaborate with the Member States to ensure that the support provided by the EU4Health Programme responds to national needs. It also aims to work with international partners and third countries in the implementation of the EU4Health Programme actions. Finally, as the EU4Health Programme will address inequalities that exist between health systems of Member States by benchmarking and providing capacity building support where needed to close the gaps.

Complementary to and in synergy with the EU4Health Programme other programmes may provide support for health policy actions, including the implementation of solutions tailored to specific national/regional contexts/needs.

4.2.2 European Regional Development Fund (ERDF)

This funding mechanism aims at improving health care systems capacity in the regions in terms of infrastructures, modernisation of the public and private healthcare sectors, and (inter)regional cooperation networks. The ERDF also provides investments in research and innovation, uptake of advanced technologies and innovative solutions, and in digitalisation, including in health. Further, it supports capacity building, technical assistance, and cross-border cooperation. This funding coincides with the needs for the development of the EHDS and, specifically, the EHDS 2.

4.2.3 European Social Fund Plus (ESF+)

This mechanism focuses more on skills development for health care staff and improved access to health care for people in socio-economic vulnerable situations, and long-term care. Therefore, this funding mechanism would be targeted more towards the development of the EHDS1.

4.2.4 Recovery and Resilience Facility

The Recovery and Resilience Facility (RRF) is a temporary recovery instrument that enabled the European Commission to raise funds to restore the immediate economic and social damage caused by the COVID-19 pandemic. 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 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.

This is interesting for a sustainable EHDS as it is also promoting a digital transition. However, it is important to find a model where the EHDS could have a permanent funding. The infrastructures that will be developed as part of the EHDS need to be constantly maintained and coordinated and hence require permanent resource allocations and funding.

To benefit from the support of the Facility, Member States must submit their recovery and resilience plans to the European Commission. Each plan sets out the reforms and investments to be implemented by end of 2026.

Once submitted, the Commission assesses Member States' recovery and resilience plans within two months after submission and translates their content into legally binding acts. Based on a proposal by the Commission, the Council to adopt the Commission's proposal within four weeks. The Council's approval leads to the disbursement of a 13% pre-financing.

4.2.5 Horizon Europe

Horizon Europe is the EU's key funding programme for research and innovation with a budget of €95.5 billion. It funds research and innovation projects on various aspects of health: health throughout the life; environmental and social health determinants; 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 Commission's proposal for a 'Health' cluster.

The EU4Health Programme will help to ensure best use of research results and facilitate the uptake, scale-up and deployment of health innovation in healthcare systems and clinical practice.

4.2.6 Digital Europe Programme

DEP support the reinforcement of digital infrastructures underpinning the wide use of digital technologies in areas of public interest. The programme will support, amongst other elements, tools and data infrastructures supporting data spaces in different sectors.

Building on that 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.

This is also a very interesting funding mechanism for the EHDS and particularly the EHDS2. Mainly focusing on the initial development phase of the EHDS, not its sustainability in the long-term.

4.2.7 Connecting Europe Facility Programme 2 Digital (CEF Digital)

This mechanism aims at closing the gaps in terms of connectivity and digitalisation. It funds highly resilient Gigabit networks to connect socio-economic drivers, including hospitals and medical centres, in areas where no such networks exist or are planned to be deployed in the near future; this will enable critical applications such as tele-operated surgery as well as the sharing of medical data. It will also bring connectivity to households to enable remote patient monitoring in a secure manner and in compliance with data protection legislation.

This will enable less developed countries or regions, in terms of digital health and connectivity, to join the EHDS and be able to participate as a node and users.

4.3 Recent calls relevant to secondary use of health data

The call under the EU4Health Programme, which closed in January 2022, includes an action grant[8] for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes. Under the grant, the consortium will design, develop, deploy and operate a network of nodes (representing different data brokers, holders and data consumers) federated by central services that may be provided by the European Commission. This pilot will investigate and establish the value of an infrastructure and data ecosystem for the reuse of health data and assess the ability to scale towards a Union-wide infrastructure, as a core component of the European Health Data Space.

Under the Digital Europe Programme, a federated European infrastructure for genomics data will be funded[9]. The main objective is to deploy sustainable and secure cross-border linkage of and access to a multitude of genomic and related phenotypic, clinical, and other datasets across Europe based on the progress achieved in the context of the 1+ Million Genomes initiative (1+MG). The call closed in February 2022.

Further calls specifically addressing the secondary use of health data are scheduled in the 2022 work programme[10] of EU4Health. They include two direct grants of major interest on European Health Data Space (EHDS), with a budget of €30 million each:

- Infrastructure and governance; primary use of data
- Infrastructure and governance; secondary use of data.

Several other funding actions are also relevant, such as the support to European Reference Networks for their integration into the national healthcare systems (€11.2 million), and various support projects.

It should also be noted that cancer, the EU mission on cancer and the beating the cancer plan are the priority which offers funding opportunities of cancer-related use cases.

[8] See the press release on 7 March 2022 of the French Health Data Hub on the project proposal and the consortium.
[9] Call on the federated European infrastructure for genomics data, DIGITAL-2021-CLOUD-AI-01-FEI-DS-GENOMICS.
[10] https://ec.europa.eu/health/publications/2022-eu4health-work-programme_en

5 National resources and financing

The European level data sharing cannot work without mature systems in Member States for data collection and access. In order to engage Member States in the secondary use, it is important that all of them also develop their capacity to benefit from the third stage, the use of data.

This chapter describes examples on the economic aspects of the secondary use of health data in Finland, the Netherlands, and Denmark. They highlight various aspects of economy 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.

The analysis of the cost impact of setting up the EHDS on data collection, data access management and data use will be completed in the final document on sustainability in early 2023. It will use fully the results and recommendations from the country visits carried out by the TEHDAS Joint Action.

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.

5.1 Finland – operating a data permit and access authority

Finland provides an example of the functioning data access and permit authority since 2020 and it is possible to estimate the costs[11] of health data management in the second stage.

Table 1. The budget estimates for Findata in 2019-2023 (done in 2020).

Year	Budget k€
2019	691
2020	5 200
2021	4 700
2022	3 200
2023	3 200

These figures have since been adjusted in the yearly budget procedure of the government but they show the order of magnitude of the costs to operate a national data permit and access authority. Table 2 gives an estimate of the different cost elements to operate Findata in 2023, as estimated in 2020, and shows the relatively small contribution of user charges.

[11] From a document in 2020:
https://stm.fi/documents/1271139/20710136/Terveyden+ja+hyvinvoinnin+laitos

Table 2. Income and expenditure of Findata in 2023 as estimated in 2020.

Cost element	**k€**	**Income**	**k€**
Personnel	2 500	User charges	750
Office rent	30	EU income and other	0
Operational costs	470		
Investment	200		
Total costs	**3 200**	**Total income**	**750**
Net costs	2 450		

Findata charges for the permit to access individual level data or for the decision on statistical data. It also asks a fee for data processing and providing the analysis environment according to the real costs[12].

Findata's charges to health data users must comply with the provisions of the Finnish legislation applicable to all authorities. Findata's total price of consists of four factors[13]

1. Fee for a decision on a request for information or fee for an information permit
2. Costs for data controllers (register holders) to retrieve and submit material
3. Working time spent on data processing (data aggregation, pre-processing, pseudonymisation and anonymisation)
4. Fee for the use of the remote access environment for data license holders.

The charges are determined based on

- Findata's real work costs, determined by the Ministry's payment regulation.
- Costs of the remote operating environment
- The register holders determine their costs based on their own rules.

The user charges have caused much discussion in Finland. In particular, clinical researchers have seen the costs as an important obstacle. On the other hand, the new system has made costs of data processing more transparent and many hidden expenses have been made visible.

5.2 Netherlands – a national investment to strengthen secondary use

The Dutch government awarded €69 million to strengthen secondary use of health data in an existing collaboration called Health Research Infrastructure (Health-RI[14]), which gives an idea of the investment needed in a highly decentralised (and privatised) healthcare system.

[12] According to the information at the end of 2020, the cost of Findata's decision on an information request or a permit was € 1 000 for an EU applicant. Data controllers determined how much they charged for data retrieval. Findata charged € 115 per hour for data processing and € 190–300 per month for the use of the remote access environment. Findata's data processing fees had been from € 115 to € 4,900 in total, and data controllers had requested from € 0 to € 69,000 for the data retrieval. Source: Finnish Medical Journal 2020:75:2574-8 (in Finnish).

[13] https://findata.fi/en/pricing/

[14] https://www.health-ri.nl/sites/healthri/files/2021-04/Samenvatting%20Groeifondsvoorstel%20Health-RI

Health data is recognised as an essential way to develop personalised health solutions faster and cheaper, and to validate these solutions and improve time to market. New knowledge in lifestyle, health, and disease together with advances in AI provide opportunities for innovative use of health data. The Dutch economy can also benefit from this.

But Netherlands lacks an integrated data infrastructure to store, combine, and reuse this data. Health-RI aims to achieve this infrastructure to strengthen the innovation and economic capacity. Realising an integrated data infrastructure is important for (1) better medical research, (2) improving the quality and affordability of health and (3) allowing biomedical industry and start-ups to compete on a global market with their products.

Countries like Germany, France, Switzerland, the UK and USA are investing millions in infrastructure to make health data available. The Netherlands wants to maintain its competitive position by investing in a high-quality data infrastructure connecting the data from university clinics with other academic institutions and health care centres. By combining genomic, blood, urine, tissue, MRI and other medical data will enable personalised medicine. This would also prevent ineffective treatments.

Health-RI will require €110 million of which €41 million will be financed from the consortium members and €69 million will come from the National Growthfund. This funding will allow for building a shared data infrastructure for 8 regional nodes centred mostly around university clinics, which provide a set of services and instruments to support end users. It is expected that Health-RI will have an impact of 1.5 billion euros in investments, efficiency gains and societal impact through better health.

Deliverables of Health-RI:
- Governance, patient control, interoperability, PPP
- FAIR data, regional nodes, central hub and international connection, federated analytics
- FAIR data catalogue, one-stop-shop, analytics software, digital workspace, support, training.

5.3 Denmark - funding mechanisms for the secondary use of health data

The basic activities of the Danish Health Data Authority are financed from the government through taxes. Researchers have to pay per hour for the services the DHDA provides and the overhead. Private sector pays the exact same price for the use of data.

There are several government grants to maintain the national registries. The clinical registries in different regions are financed by the regions. All public hospitals are run and financed by the budget of the regions.

The Coordinating Body for Registry Research (KOR) provides €1.5 million for the registries to provide services to researchers. The funding is not to maintain or run the registries but to finance part of the service they are providing to researchers (handling applications and constructing datasets for researchers).

The Novo Nordisk foundation finances development of innovative projects and as soon as these projects are successful, the government takes over their funding and sustains them. Biobanks, for example, were initially dependent on the Novo Nordisk foundation but now they are permanently funded €3.5 million from the budget of the Ministry of Health. Sustainability is now secured. They store and hand out samples to researchers for free thanks to the government funding.

The Danish Genome Centre is also funded by the Novo Nordisk foundation. It is on the annual budget of €40 million/year but to be sustainable it will get more funding after 2024 from the Ministry. As a part of the Ministry, it remains completely independent from the private sector.
The Danish Medicines Agency charges a fee for pharmaceuticals, medical devices, pharmacies, distributing medicines, and receive a significant amount from the fee of the EMA.

The Novo Nordisk foundation highlights the benefits of a public-private partnerships for improving secondary use of health data. It focuses on innovation and helps financing the development of innovative projects. Once the project is established, the Ministry of Health starts sustaining it with an annual budget.

In the Novo Nordisk model, all profits from companies go to the foundation. The benefit is the greater good. The Novo Nordisk foundation mainly funds activities in the core areas of its scope. It is important that it can add money to the national funding for research.

However, some say that it also has its own agenda. The foundation can do major initial funding but then it pulls out and the Danish state needs to maintain and sustain this.

6 Financing of current EU data sharing mechanisms

This chapter describes some existing EU data sharing mechanisms in more detail and analyses their cost structure. They illustrate relevant issues in funding the exchange of health data in the primary or secondary use.

Each mechanism is described in a table which briefly describes the mechanism and analyses their advantages and disadvantages.

The mechanisms include agencies and other types of EU level mechanisms or projects:

1. Infectious disease data collection and sharing by the ECDC - TESSy
2. Sharing health data in primary use - MyHealth@EU
3. European Reference Networks and rare disease clinical consultation system - CPMS
4. Elixir - European Life-science Infrastructure for Biological Information
5. Darwin - Data Analysis and Real-World Interrogation Network
6. Population Health Information Research Infrastructure (PHIRI).

6.1 ECDC and TESSy

Mechanism	1
Mechanism name	European Centre for Disease Prevention and Control: Data collection and sharing: the European Surveillance System (TESSy)
Highlights	The ECDC's TESSy is an example of an agency-based financing of a sustained data collection and exchange mechanism, funded from the EU budget.

Description

TESSy is a highly flexible metadata-driven system for collection, validation, cleaning, analysis, access and dissemination of data for public health action.

There are 3 types of access: 1) "direct" for nominated individuals; 2) access to subsets of data: for external researchers and the same group entitled to direct access; 3) unrestricted access to aggregated published data.

Since June 2021, TESSy has a new entry point through the EpiPulse platform and will be progressively replaced by EpiPulse between 2021 and 2023.

EpiPulse is a single platform for European public health authorities and global partners to collect, access, analyse, share, and discuss infectious disease data for threat detection, monitoring, risk assessment and outbreak response, launched by ECDC in June 2021, integrating surveillance systems that were previously independent: The European Surveillance System (TESSy), the five Epidemic Intelligence Information System (EPIS) platforms and the Threat Tracking Tool (TTT).

All operational costs related to TESSy, as well as investment or development, are funded from the annual EU budget. The expenditure consists of staff, consultants' and subcontractors' time. ECDC outsources some activities which include consultancy, data generation on epidemiology and public health action.

Economic model and national financing

Consolidating surveillance, increasing its efficiency and enhancing the outputs and their impact, were in the centre of ECDS's Long-term surveillance strategy for 2014–2020. This required better data quality provided, while at the same time making reporting to the ECDC less burdensome for the Member States.

ECDC, however, cannot directly fund the development of Member States' public health infrastructure, it helps by sharing technical expertise, ad hoc advice and active support in tapping alternative funding sources.

Strategic objective 2 of ECDC's current strategy for 2021–2027, supports the countries to strengthen their capacities and capabilities to make evidence-based decisions on public health policies and practice. The Centre will focus on a further engagement with Member States in a continuous dialogue and involvement in ECDC activities. This approach should also help Member States and the Commission to identify EU mechanisms such as ESF+ (European Social Fund) or Digital Europe that could be tapped into funding communicable disease prevention and control systems as part of entire national health systems.

Sustainability

TESSy is a highly flexible metadata-driven system for providing surveillance data, data analysis and scientific advice on more than 50 notifiable communicable diseases and conditions, disease outbreaks and public health threats. TESSy is maintained, operated, and developed by ECDC.

TESSy has no dedicated budget as it is one of the key tools deployed by ECDC in its role and functions of a European agency. Its sustainability is based on the financial resources allocated for ECDC, a decentralised agency, which is set up for an indefinite period.

Despite being backed by a legally binding instrument and being an agency, the EU governance framework remains a work in progress. ECDC as the coordinating agency is critical for countering cross-border health threats which need coordinated action across national borders.

ECDC draws on the expertise and knowledge of its expert staff, sustained pan-European disease networks of national public health bodies.

Advantages and problems

- TESSy is financed through a budget-based funding. a mechanism available to an EU agency responsible for public health action. It can be seen as the good funding model of EHDS2.
- There is no funding for national data collection.
- Currently the costs are not visible as they are a part of the agency's operational budget.
- Despite the relatively stable situation, ECDC may appear understaffed and under-budgeted.

Sources

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3. https://eufundingoverview.be/funding/european-centre-for-disease-prevention-and-control-ecdc-decentralised-agencies
4. https://www.ecdc.europa.eu/sites/default/files/documents/LTSS-revised_0.pdf

5. https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-Strategy-2021-2027.pdf
6. RENDA, A., & CASTRO, R. (2020). Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic. European Journal of Risk Regulation, 11(2), 273-282. Doi:10.1017/err.2020.34
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8. Discussion with ECDC staff experts about TESSy, TEAMS, 01.12.2021

6.2 MyHealth@EU

Mechanism	2
Mechanism name	MyHealth@EU – exchange of patient data
Highlights	MyHealth@EU is an example of the data exchange mechanism set up using project-based funding. It evolved to a sustained mechanism with costs shared between the EU and Member States.

Description

MyHealth@EU or the eHealth Digital Service Infrastructure, as it was called earlier, represents digital health services which allow EU countries to exchange health data to improve care of patients. It is underpinned by Directive on Patients' Rights in Cross-Border Healthcare, and in particular its Article 14.

MyHealth@EU is a cross-border health data sharing mechanism that is already in operation. Currently, participating countries are exchanging e-prescriptions and patient summaries using the system but there are plans to extend the categories of data to be exchanged, such a laboratory results and discharge letters.

MyHealth@EU was made possible by Member States' common framework for action and their agreements approved by the eHealth Network. It includes the ICT infrastructure and services created jointly by the Commission and Member States.

The system consists of national contact points and the EU level coordination mechanism.

There have been discussions about the role of the system in the secondary use of the data generated through the system, but it is unlikely that MyHealth@EU data can ever be used beyond operational statistics.

The system was originally designed in a project epSOS of the Member States. The preparatory work was continued in other projects that built the EU-level infrastructure and core services as well as the national contact points for eHealth (generic services).

The CEF budget run over several years and provided subsidies to member States for setting up of the national nodes.

Economic model and national financing

In the early project phase, the funding came from the Connecting Europe Facility (CEF), which funded the epSOS project, with a total budget of €38 million.

In the second phase, when the Member States started building their national nodes, the subsidy was in principle 75% of the costs but several countries reported that the maximum EU subsidy of €1 million per country was not enough.

In addition, the Commission has used its resources for EU coordination and auditing of the national implementation.

There are no fees for using the system: it is provided as a free service to the EU citizens, funded from the European and national budgets. The EU covers the central and coordination costs from the EU budget. The participating Member States cover their own cost for running the national nodes.

Sustainability

The legal provision in the Directive on Patients' Rights gives some continuity to the service but ultimately its continuity largely depends on the willingness of the participating Member States to continue financing their national node. This will be determined by the actual use of the service and the benefit to patients.

The Court of Auditors criticised in 2018 the implementation of the cross-border exchange of health data and noted how difficult it is to fulfil the ambitions, which will in the long run determine the fate of the service.

Advantages and problems

- The system has been built incrementally which has allowed its design to evolve. This has been important in a project whose scale and ambition has been unprecedented.
- Due to the project-type funding, there has been limited certainty of the future of the service.
- Being an endeavour into an unknown territory and technologically ahead of many Member States, forging the cooperation and developing the technical solutions has been slow and relatively burdensome for the EU.
- Calculating the benefits (estimating the number of beneficiaries) and costs of services is not clear and there are questions who ultimately pays for them. However, those citizens who use the service, clearly benefit.
- The COVID-19 pandemic largely stopped the travel at a time when the system was starting and expanding, thus impeding the use of the system.
- The sustainability of the system is not underpinned by clear legal provisions EU level.

Sources

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2. https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en
3. https://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/cef-telecom-projects
4. https://op.europa.eu/webpub/eca/special-reports/cross-border-health-care-7-2019/en/

6.3 European Reference Networks and the CPMS

Mechanism	2
Mechanism name	European Reference Networks: Clinical Patient Management System
Highlights	The CPMS of the European Reference Networks is a sustained clinical consultation mechanism on rare diseases between the participating

	hospitals. The hospitals and Member States cover their costs. The EU-level funding is mainly from the health programmes.

Description

The European Reference Networks (ERNs) are virtual networks linking healthcare providers across Europe, with the objective of improving discussion on complex rare diseases and improving care for patients with them. The ERNs are underpinned by Directive on patients' rights in cross-border healthcare.

The ERNs were launched in 2017. They receive financial support from several EU funding programmes, including the Health Programmes, the Connecting Europe Facility and the Horizon programmes. The running of the ERNs is driven by the Member States.

The European Reference Networks consists of 24 networks, each of which focus on a particular rare disease group. Over 900 clinics from 300 hospitals are members in the networks. The expansion of the reach of these networks in on-going.

In order to carry out distributed, virtual clinical consultations on patient cases, a digital, secure consultation system was created, called the Clinical Patient Management System (CPMS). The CPMS has been operational since 2017. The cross-border use of clinical data, even if pseudonymised, is unprecedented in the EU.

Economic model and national financing

The financing of the coordination of the ERNs has been mainly from the third health programme as operating grants and the EU-level infrastructure from the CEF programme.

The operation of the clinics is funded from national sources. The participating Member States cover their costs.

There is no income model for the system, and the CPMS is provided as a free service to the EU healthcare systems.

In addition, the ERNs have benefitted from project-based research funding from the Horizon 2020 and the third health programme.

In the European Parliament, there has been calls for further EU financing for healthcare actions in order to benefit the poorer regions of the EU. The European Commission has not seen this possible under the current legal framework.

Sustainability

The logic for the ERNs stems from Directive on Patients' Rights which gives them legal sustainability.

However, the continuity of the system depends on the EU level financing and there are no provisions for sustained financing. The importance of the ERNs for an underserved patient group and the clear EU added value favours maintaining the EU financing.

As noted by the Court of Auditors in 2018, the actual use of the service needs to be evaluated to determine the benefits and the economic costs of the service.

Advantages and problems

- While the EU level financing has been relatively continuous, the national financing has been more of a problem. According to the Commission, the work of the ERN clinics should be seen as the normal work of the national healthcare.
- However, the networks themselves have felt that the EU level financing has been limited.
- The ERN funding has been project-type funding, as was the case for the communicable disease monitoring in the 1990s. However, the operation of the rare disease networks is by definition continuous.
- It would be of utmost importance that the ERNs themselves demonstrate the value and benefits from their actions to justify their continuous funding.

- The project-type funding causes unpredictability for the available resources and all new development depends on ad-hoc resource.

Sources

1. https://ec.europa.eu/health/european-reference-networks/overview_en
2. https://op.europa.eu/webpub/eca/special-reports/cross-border-health-care-7-2019/en/

6.4 Elixir

Mechanism	4
Mechanism name	ELIXIR - European Life-science Infrastructure for Biological Information
Highlights	ELIXIR is a research infrastructure whose central elements are financed by the participating Member States, who finance their national nodes, supported by ad-hoc EU grants.

Description

ELIXIR is a distributed infrastructure in the domain of life science focusing on biological information. ELIXIR operates with a central hub and organisationally independent nodes that are distributed across the different partner countries. ELIXIR Services are delivered by institutes associated with the nodes in ELIXIR's Member countries. The ELIXIR Hub provides an administrative governance structure, which carries out scientific, technical and administrative coordination tasks in addition to the delivery of core services.

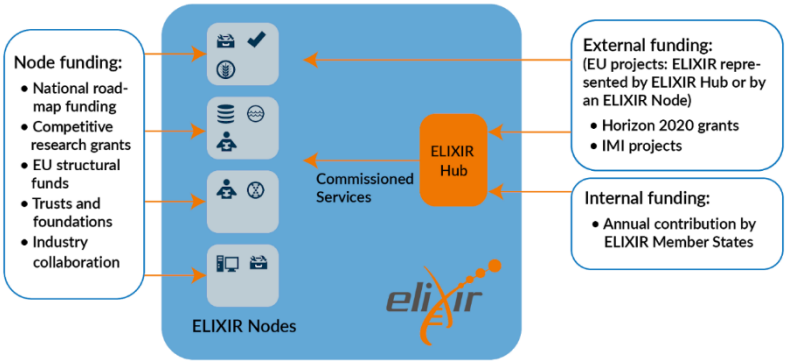
This is an option that could also work as an architecture of the EHDS2, and Elixir could have the role of a node in the EHDS and provide its services.

Elixir has gone through different phases to become an operational Research Infrastructure. These were implemented through funded projects while being part of the European Strategy Forum on Research Infrastructures (ESFRI) roadmap:

- Roadmap entry-*2006*
- Preparation phase project-*2007-2011*
- Interim/transition phase project-*2011-2013*
- Implementation/construction phase project-*2013-2020*
- Operation start-*2014*

Once operational, Elixir has had a mixed model for funding (see figure) on three different levels:

- External funding, mainly from grants.
- Internal funding mainly from the participating countries through annual membership fees; and
- Additional specific funding for the nodes.



The external and internal funding are mainly used for costs of the central Elixir hub.

This funding structure could be used by the EHDS. Maintenance of a central hub or office to be funded at EU level, while the distributed nodes of the EHDS could be funded nationally.

Economic model and national financing

The Member States provide financial contributions that form the sustainable source of funding of the ELIXIR Hub. Each State contributes annually an aggregate amount of funds to the capital expenditure and to the current operating expenses of the ELIXIR Hub. The Member State contributions are defined in accordance with a scale that is fixed every three years by the ELIXIR Board. The scale is based on the average Net National Income at factor cost (NNI) of each State for the three latest preceding calendar years in accordance with OECD statistics.

Capital value: 125 M€

Estimated operation costs: 95 M€/year

Sustainability

In its operational structure ELIXIR relies on the legal personality of the European Molecular Biology Laboratory (EMBL). This allows ELIXIR to take advantage of EMBL's privileges and immunities. Nevertheless, ELIXIR activities are carried out independently from EMBL, governed by the ELIXIR Board and based on separate accounts. ELIXIR Member States therefore only finance those activities that are related to ELIXIR. With these privileges Elixir has the possibility to function while applying and receiving different types of funding. In addition to the constant financial support from the ELIXIR member states, ELIXIR has been very successful in receiving funding through competitive calls due to its large network of active nodes and the scientific expertise it has built through the past years as a leading research infrastructure in the field.

Advantages and problems

- The advantages of the process that Elixir took to become operational is through the ESFRI roadmap; working through the phases ensures that all aspects are considered and being part of the ESFRI roadmap opens possibilities for funding that is directed towards ESFRI projects. This may not be possible for the EHDS as the ESFRI roadmap focuses on research infrastructures.
- A main weakness of the Elixir funding model is the constant need for national funding to keep the nodes functional and providing services to the research infrastructure and its members.

Sources

1. https://www.elixir-europe.org
2. https://www.esfri.eu/about

6.5 DARWIN

Mechanism	5
Mechanism name	Data Analysis and Real-World Interrogation Network - DARWIN EU
Highlights	DARWIN will be a network financed by the EMA, with an aim to be sustainable over time.

Description

The aim of the DARWIN project is to establish a sustainable platform that will enable the access and analysis of real-world healthcare data across EU. This will help the evidence-based decision making.

DARWIN will work with a distributed network of nodes, data holders that are all linked to an orchestrator, a third-party coordination centre. It is important to note that in DARWIN, data doesn't have to leave from the data holder as it is a federated access and analysis system. To enable this, there is a standardised data model for fast analysis of the data.

This is an option that could also work as an architecture of the EHDS2. DARWIN EU could also become a node itself to the EHDS.

A 3-year (2021-2023) funding of €20 million was provided through the EU4Health Programme, for infrastructure and governance.

To develop real world data methodologies and capacity building there is also funding from the Horizon Europe that started in 2021.

Economic model and national financing

Establishment and upscaling phase - €20 million for 3 years

- Setting the DARWIN EU services
- Business Processes & Operating Model
- Catalogue of standard data analyses
- Assuming operation of the catalogue of Data Sources
- Data Use Agreement
- Onboarding Document
- Business plan
- Change Management Strategy & Approach
- Start running pilots/studies

Operating phase - €16 million/year from EMA fees

- Run Routine/Recurring, Simple & Complex Studies
- Recurring updates of the catalogue of real-world data sources and of metadata/quality information about data sources
- On-boarding of new data holders

EMA charges fees for its services. For example, the Agency charges fees for applications for marketing authorisation, and for variations and other changes to marketing authorisations, as well as annual fees for authorised medicines.

Sustainability

To ensure maintenance from 2023 onwards and the sustainability of the DARWIN project in the long-term, the funding is based on EMA fees.

Therefore, there is a need to revise the EMA fee regulation that would cover both maintenance of the infrastructure and the governance and evolution of the platform. Funding is important to maintain the quality of the data that will be available for analysis through the DARWIN EU and to meet the network needs for real world evidence.

Finally, building and operating the DARWIN EU will require the involvement of EU patient and healthcare professional organisations.

Advantages and problems

- The main advantages of the DARWIN EU relate to the national and EU regulation of medicines:
  - Drug development: disease epidemiology, unmet need, historical controls, planning
  - Authorisation: contribution to benefit and risk decision making, controls, extrapolation to general & special populations
  - On market: benefit and risk monitoring, extension of an indication.
- Additional benefits will come as EU partners participate and access the platform. The DARWIN EU will support and benefit from the European Health Data Space.
- Regarding national governments, DARWIN EU supports evidence-based health policies and improved healthcare systems.
- For the patients in the EU, the DARWIN EU will enable faster access to innovative medicines and safe and effective use.

Sources

1. https://www.ema.europa.eu/en/documents/presentation/presentation-proposal-darwin-eu-data-analytics-real-world-interrogation-network-parlett-ema_en.pdf

6.6 PHIRI

Mechanism	6
Mechanism name	Population Health Information Research Infrastructure (PHIRI)
Highlights	A research infrastructure funded by EU that is piloting federated data analysis through use cases, providing an example that may be further used by EHDS.

Description

PHIRI for COVID-19 is a project that supports research across Europe through the identification, access, assessment and reuse of population health data. PHIRI allows for better coordinated European efforts across national and European stakeholders to generate the best available evidence for research on health and well-being of populations as impacted by COVID-19 to underpin decision making. In doing so, PHIRI also lays the foundation for a federated research infrastructure on population health.

More specifically, PHIRI adopts a federated architecture that is piloted by 4 different use cases of immediate relevance on COVID-19 impacts (on vulnerable populations, on perinatal health, on mental health and delayed cancer care) by conducting research. In over 20 datahubs, data is mobilized and ready to be analysed in a distributed manner.

Economic model and national financing

Currently, PHIRI is (100%) funded by the European Union's Horizon 2020 research and innovation programme (5M). It is a 3-year project that runs from November 2020 to October 2023.

The experience of the PHIRI use cases provides an estimation on what is needed for cross border health data sharing through federated analysis with a central orchestrator, based on a research question across participating data hubs.

1. Human resources

   For central coordination, 2 FTE data engineer and scientific researcher per year for 2 years:

   - Data Engineer – 8.000,00 per month, 96.000,00€
   - Data Scientist – 7.000,00 per month, 84.000,00€

   For each institute participating in the use case, 6 PM is estimated to carry out the use case:

   - Data Engineer per hub – 8.000,00 per months*, 48.000,00€

2. Infrastructure costs

   Around €130,000 per year for e-infrastructure subcontracting (or in-kind) budget prospective data owner institutions joining the use case to ready their sites for service integration and compliance with data policy and data management plans

   - Infrastructure costs per hub, 120.000,00 €
   - legal support for legal entity per hub, 10.000,00 €

3. Data access
   - Data access per country participating**, 10.000,00€

*The data Engineer cost per hub is estimated based on the cost in Belgium, but this could differ considerably by country.

**The data access cost here is estimated for Belgium but could highly differ per node.

Sustainability

PHIRI unites Pan-European research excellence and national expertise on health data and information beyond COVID-19 and constitutes a firm backbone of Pan-European research networks and national nodes. PHIRI will continue its operation as DIPoH and function with a central coordination office and builds on a backbone of national nodes that are spread across EU countries, and pan-European domain specific research networks and their research communities.

PHIRI and DIPoH can play the role of a node within the EHDS and support sharing and the (re)used of population health data- as it is an integral part of a wider health data landscape.

Advantages and problems

- The advantage of PHIRI is in the services it provides to the population health information stakeholders and landscape.
- These can also support the EHDS' mission in facilitating the (re)use and sharing of (population) health data.
- More importantly is the implementation of a safe and federated model that is currently piloted within PHIRI, which can provide input to the structural development of the EHDS.
- A weakness of PHIRI is its project-type nature, binding it to a certain time period of funding.

Sources

1. www.healthinformationportal.eu
2. www.inf-act.eu
3. www.bridge-health.eu

7 Discussion on the cost of and funding for the EHDS

This preparatory document highlights issues related to the sustainability of any EU-level health data access and sharing system, and the complexity of analysing sustainability.

Building a European data access and sharing system has an impact on the national data collection and access mechanism, their development and consequently on the costs to the governments. It will raise questions of funding the development of the national systems as well as costs of joining the European data exchange.

Sustainability of EU action has been an important and difficult topic in many EU's health projects and initiatives. The problem of maintaining new initiatives is old and far from resolved. It has been discussed in health data sharing projects[15] and the 1+ Million Genomes Initiative[16].

Framework for analysing sustainability and its dimensions. In this document, TEHDAS discusses a framework of three stages and the linkage of national costs to the cross-border data sharing. The TEHDAS Joint Action will continue studying various aspects of sustainability in the next document (D4.3), scheduled for early 2023, building on the framework and five dimensions of sustainability.

1. Clear legal basis. This is expected to be created through the forthcoming legal proposal.
2. Governance and organisational arrangements are well defined and functional.
3. Technical and operational infrastructure can be maintained.
4. Financial sustainability: funding and income at European, national and local levels.
5. Human resources to underpin action. This includes capacity building and training for data analysts, data scientists and data literacy of all health professionals.

Estimating the resources and funding needed to set up the European Health Data Space. This document discussed examples on both European mechanisms and national solutions, which point to the scale of costs and resource needs to be expected. With further data and the use of the analytical framework, it may be possible to extrapolate the available fragmented estimates to a European-wide estimate.

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. The 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.

The burden sharing between the EU and the Member States in funding 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 the EU and

[15] The project BRIDGE Health investigated options to create an organisational entity to strengthen the EU health information system. Its findings suggested setting up a new structure, possibly in the form of a research infrastructure. The successor to BRIDGE Health, the InfAct Joint Action, investigated different services of such an infrastructure and developed a business plan for a research infrastructure on population health that would facilitate health information and the use of health data across EU countries.

[16] The Beyond 1 Million Genomes Project (B1MG) supporting the 1+ Million Genomes Initiative has analysed the long-term sustainability of the initiative and listed various financing and funding mechanisms.

national sources. While the European coordination action needs 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. Even in situations where the EU-level coordination costs are covered, the investment in and maintenance of national nodes for EU work can be difficult.

Predictable, fair and sustainable EU funding. Traditionally EU projects are financed under time-limited, short-term contracts on ad-hoc basis. This has been also the case in the initiatives analysed in this document. The project-based funding brings many problems, including a potential overlap and inefficient use of resources. The national contributions in many EU projects are quite high and consequently many organisations, even Member States, are excluded as they are not able to provide the national contribution.

Only the two agency-based data sharing mechanisms seem to have escaped the problems (TESSy and DARWIN). Expanding the ECDC or establishing an agency or a similar sustainable structure for the EHDS needs to be seriously looked at.

The increase of the EU budget for health, as welcome as it is, creates resource problems at national level. With more and bigger projects, the national contribution increases. Many Member States lack mechanisms for national funding. Further, as many of these projects are similar, the same people are involved in multiple projects and Member States run out of human capacity even if the funding there. Therefore, the EU funding should seek to create permanent and sustained capacities to implement secondary use of health data both at EU and national level.

The maturity of national nodes to join the network varies. The funding needs to consider the very different situations of the secondary use of data in Member States. It is important to create incentives and opportunities for progress in the use of health data regardless of the starting position. Through the country visits, TEHDAS is collecting the needs for training and capacity building in Member States and associated countries in order to incorporate it in the funding needs.

Highlight the benefits of secondary use of health data[17]. Investment in access and sharing of health data for secondary propose is not only subject for the healthcare sector but for all other sectors. European governments should be encouraged to participate in the development of the EHDS2. Proper communication would encourage governments to look at EHDS2 as a subject of joint interest of sectors responsible for healthcare, research, industry and other sectors and demonstrate benefits from investment in health data use. A macroeconomic analysis visualising benefits of sharing health data in the EHDS2 might also help in providing guidance and justification to involve all stakeholders.

[17] See for example Marjanovic S, Ghiga I, Yang M, Knack A. Understanding value in health data ecosystems - A review of current evidence and ways forward. Rand Europe for EFPIA 2017.