



Towards  
European  
Health  
Data  
Space

Milestone 5.8

# **Potential health data governance mechanisms for European Health Data Space**

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## 1 Executive summary

The European Union has the strategic aim to create a single market for data. Data is an essential resource for economic growth, competitiveness, innovation, job creation and societal progress in general. Health data plays a fundamental part of this strategy, with the ambitious goals of promoting much wider use of data in the health sector.

EU health policies have evolved through new legislation and by creating sustainable new actors within it. Outstanding developments here included the creation of the European Medicines Agency (EMA) in 1995 and the European Centre for Disease Prevention and Control (ECDC) in 2005. The Directive on the Patients' Rights in Cross-Border Care in 2011 paved the way for the development of the European Reference Networks, eHealth Network, and Health Technology Assessment.

The political will expressed by the EU leaders in 2020 has hastened the work on the European Health Data Space. This process will include new legislation and likely new actors in the use and reuse of health data. The success of new developments depends greatly on the governance mechanism put in place.

The TEHDAS<sup>1</sup> Joint Action proved<sup>2</sup> that health data is a special case for its governance. While such particularities do not decrease the need for data sharing within the health sector, the nature of the data and the implied need for safeguards should be taken into account.

This document presents some existing or proposed mechanisms for governing the secondary use of health data in the EU. It demonstrates that there are already multiple mechanisms governing different types of data or for specific use cases. This risks a fragmentation of governance, inconsistent approach to data, and waste through overlapping efforts. Easy-to-read tables illustrate eight governance mechanisms and their pros and cons from the perspective of the secondary use of health data.

The governance mechanisms are analysed using the concepts of regulatory intensity, level of centralisation, regulatory autonomy, legislative intensity, and institutional constellation. Other relevant factors are likewise taken into account. The mechanisms presented in this document are explicitly graded for legislative intensity. It shows that sustainability and impact are achieved through higher intensity.

The scope of governance can range from health data collection for secondary use to promoting data analytics and innovation use, through procedures of granting the permit to access data, combining and making data sets available, and providing a secure environment. The question of this scope is discussed in the context of a possible future health data governance mechanism. Setting the scope of the EU health data governance for the cross-border secondary use is the key riddle in TEHDAS as well as for the European Commission, who commands the right of initiative in the EU.

One key conclusion seems obvious. While the current mechanisms are fit for their specific purpose, they cannot alone support the single market for health data nor the secondary use of health data for research, innovation and decision making. Each mechanism has been designed and optimised for a specific use case. Multiplying existing mechanisms for

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<sup>1</sup> Joint Action Towards the European Health Data Space (TEHDAS)

<sup>2</sup> TEHDAS. Why health is a special case for data governance ([M5.7](#)), 2021

additional purposes and use cases would only add to the fragmentation of effort, when all these mechanisms struggle with similar legal, technical, organisational and semantic issues.

However, hard questions remain: Should the future European Health Data Space governance mechanism become the umbrella for many of the mechanisms described in this document? Backed by a higher legislative intensity and a broad mandate, could the new mechanism streamline how data is accessed, what technical standards are used, and what data quality measures are required from other mechanisms? Or would the future EHDS governance function best with a limited scope to solve a specific issue in access to data, such as the cross-border data access permits?

This document sets the ground for further debate on governance. It will be followed by a concluding document towards the end of 2022. It will dig deeper into how health data should be governed in the future European Health Data Space.

## 2 Context

The TEHDAS Joint Action studies various aspects of data governance in a dedicated work package (WP5). It will produce two preparatory documents to underpin the discussion on the forthcoming legislation on the European Health Data Space (EHDS). The final results of the work will be published in early 2022 (in a document called Deliverable D5.4).

This document builds on the earlier document<sup>3</sup> “Why health data is a special case for governance”, which explained the specificities of health data in comparison to data in many other fields. It also answered the question why governing health data in the context of European data spaces requires dedicated legislation and a specific Health Data Space.

The current document seeks to respond to three questions: (1) How these specificities point to how the governance of the European Health Data Space needs to be designed and (2) Who are the actors currently involved. Finally, it seeks to study the question (3) can all health data exchange in secondary use can be governed by one mechanism?

In order to answer these questions, this document considers relevant proposals from the European Commission, in particular the proposal for the Data Governance Act and the Roadmap and Initial Impact Assessment (IIA) on the EHDS. These are put into context with each other and other acts currently under discussion and relevant to the secondary use of health data. These proposals have suggested or discussed data governance elements, such as the eHealth Network, the European Data Innovation Board, and a network of national, designated data permit and access bodies.

Discussing options for the EHDS governance model serves multiple goals. First, discussing governance models gives an idea as to which model fits the health data specificities that were identified in the earlier paper, in a sustainable and future-proof way. Second, the multiplicity and heterogeneity of the existing or proposed governance models is demonstrated. Their strengths and flaws are discussed systematically. And third, it demonstrates that a possible new governance model for the EHDS enters into an already populated patchwork of governing mechanisms and not in a legislative vacuum. It will inevitably need to pertain to other governance models, possibly superseding (elements of) these.

The TEHDAS Joint Action focuses on the secondary use of data but inevitably the discussion needs to take into account also the primary use of data, which is where the data is generated. The Commission’s proposal on the EHDS will likely cover both aspects.

This document describes basic elements on Who and How. It makes no recommendations on or comparison between the mechanisms. It does not strive to be exhaustive in covering all possible mechanisms. It avoids taking a position on the current political discussion regarding data governance or EU competency on health policy.

Additionally, several aspects will be addressed in other TEHDAS outputs: The sustainability issues will be discussed by the Work Package 4 and technical aspects of the data exchange infrastructures will be covered by the Work Package 7.

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<sup>3</sup> TEHDAS. Why health is a special case for data governance (M5.7), 2021

### 3 Commission's proposals relevant to secondary use of data

#### *Data Governance Act complementing the Open Data Directive*

As the first of a set of measures announced in the 2020 European strategy for data, the proposed Data Governance Act (DGA) complements the Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (Open Data Directive). The DGA proposal addresses data held by public sector bodies that is subject to rights of others and therefore falls outside the scope of the Open Data Directive. It aims at facilitating data sharing including by reinforcing trust in data sharing intermediaries that are expected to be used in the different data spaces.

#### *DGA and interaction with the GDPR and ePrivacy Directive*

The proposed DGA covers different types of data intermediaries, handling both personal and non-personal data. With that, both the General Data Protection Regulation (GDPR) and ePrivacy Directive come into scope, providing a potentially comprehensive legal framework. The DGA is intended to regulate the following situations (European Commission, 2020)<sup>4</sup>:

- *Making public sector data available for re-use, in situations where such data is subject to rights of others.*
- *Sharing of data among businesses, against remuneration in any form.*
- *Allowing personal data to be used with the help of a 'personal data-sharing intermediary', designed to help individuals exercise their rights under the General Data Protection Regulation (GDPR).*
- *Allowing data use on altruistic grounds.*

#### *DGA, Data Innovation Board and Data Protection Board*

To implement this proposed comprehensive data governance framework successfully, the DGA proposes the inception of a European Data Innovation Board, in the form of an expert group. This Board should consist of representatives of the Member States, the Commission and representatives of relevant data spaces and specific sectors (such as health, agriculture, transport and statistics). The European Data Protection Board should be invited to appoint a representative to the European Data Innovation Board.

The Board's mandate would be to support the Commission in coordinating national practices and policies on the topics covered by this Regulation, and in supporting cross-sector data use by adhering to the European Interoperability Framework (EIF) principles and through the utilisation of standards and specifications.

#### *DGA and need for sectoral regulation - European Health Data Space*

The creation of health sector specific regulation – the proposed European Health Data Space (EHDS)– could cover the instances where the proposed DGA presumably falls short, for

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<sup>4</sup> European Commission (2020). Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). 2020/0340(COD).

example due to stricter conditions that may be in force for certain types of non-personal data that have been identified as highly sensitive.

### *The Inception Impact Assessment - European Health Data Space*

The Inception Impact Assessment (IIA) on the creation of the EHDS was published on 4 December 2020 as part of the general effort to create common data spaces in nine areas of interest, identified in the European strategy of data presented in February of 2020. The IIA states as an objective to ensure access, sharing and optimal use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, timely, transparent and trustworthy way, and with an appropriate institutional governance.

The initial feedback period ended in February 2021, receiving 151 replies from a broad array of stakeholders. The public consultation period ran from 3 May until 26 July 2021, its questionnaire was divided into three sections: i) Access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making; ii) Digital health services and products; and iii) Artificial Intelligence (AI) in healthcare.

The first section is the most relevant in light of the JA TEHDAS project, section 1.2. specifically, having a set of questions on mechanisms facilitating the sharing of health data for secondary purposes, eg. appropriate governance mechanisms, incentives for businesses, the potential of an EU body, and the benefits of the EHDS. The public consultation will feed into an Impact Assessment. This will likewise assess the workings of the eHealth Network, the provisions of the cross-border healthcare Directive, coherence with the DGA and other acts, and the necessity of new EU legislation, to be finalised by mid-2021. A legislative proposal is expected in Q1 2022.

### *Subsidiarity*

In line with article 5(3) of the TEU, in areas of shared competences between the Commission and the Member States, the Union can only act if the objectives of the proposed action cannot be sufficiently achieved by the Member States. Therefore, an Impact Assessment on a novel legislative proposal elaborates on the appropriate legal basis for EU-level action as derived from the Treaties, and is complementary to an analysis of the proportionality of the measure in question.

Proposals for public health policies, an area where the legislative competences of the Commission have been specified and restricted under article 168 of the TFEU, will require a more pressing need than most other policy areas for well-founded reasonings to justify a legislative intervention at the European level. Such a description should assess whether action at the national level would have been sufficient to achieve the initiative's objectives, taking into account the more fundamental goal of ensuring that decisions are made at a level as close as possible to EU citizens and only at the broader Union level when required due to reasons of scale and effects.

The IIA refers to two articles from the TFEU, article 114 on the EU's competence to enact measures to harmonise the workings of the internal market and article 16 on the right of personal data protection.



Regarding health data, the free movement of people, products, and services gets ensured when EU citizens can take their health data across the borders of the Member States and have cross-border access to such data.

Currently, there is still fragmentation in access, sharing, and the use of health data at the national level. Diverging and often conflicting national laws impede access to data in a cross-border setting for patients, researchers, and policy-makers. The situation curbs interoperability, negatively affects the development of Artificial Intelligence (AI) systems, and impedes digital health progress. The cross-border movement of digital services and products as well as the cross-border access to health data is limited, which negatively influences the free movement of EU citizens as they cannot freely transfer personal data across the Member States.

These issues amplify the necessity of action at the European level by the Commission, any measurement in compliance with article 16 of the TFEU due to the provisions on personal data rights of the GDPR.

#### *Problems of the current legislative system*

Complementary to the issues identified above, the IIA also elaborates on a set of more specific problems that the initiative aims to tackle, a fragmented governance system in the secondary use of health data mentioned as one issue due to diverging interpretations of the GDPR and different levels of maturity with regards to the institutionalisation of relevant national infrastructures.

The horizontal framework of the DGA only partly curbs such issues, problematic in light of the notion that access to health data from public and private organisations might positively influence evidence-based policy-making and regulatory action. As the baseline scenario is considered insufficient, the document briefly mentions the aim of creating a legal governance framework covering the access and exchange of health data and a set of policy options which might foster such practices: revising the mandate and scope of the eHealth Network, complementing the DGA, the designation of national health bodies as sectoral counterparts of the authorities supervising data intermediary services in line with the DGA, a horizontal framework in which sectoral bodies are brought together at the European level, supporting public authorities in the access of health data.

#### *Building a European Health Union*

References to the EHDS are made in three legislative proposals collectively considered the first step towards building the European Health Union as identified in the Communication on Reinforcing the EU's resilience for cross-border health threats published on 11 November 2020.

The first one is on amending the mandate of the ECDC, which mentions the EHDS in the altered article 5 on network activities with the task of ensuring the interoperability of digital surveillance platforms with digital infrastructure and the view of integrating the work of the ECDC into the EHDS.

The second is the proposal on revamping the mandate of the EMA, with the notion of integrating EMA data on the usage and shortage of medicinal products and medical device into the EHDS, albeit the precise role as a data controller or processor is yet to be specified.

The integration of the agency into the EHDS likewise feeds into the functioning of the COVID-19 EMA Pandemic Taskforce.

The third proposal is on upgrading Decision 1082/2013/EU on serious cross-border threats to health, which briefly mentions that the legislation will provide input and synergies by facilitating the sharing of data, reiterated by the two abovementioned proposals.

#### *The AI Regulation*

A proposal and two related legislative activities on Artificial Intelligence (AI) are discussed in the IIA of the EHDS against the back drop of providing a horizontal ethical framework in the future usage of AI. A feedback period on the proposed AI regulation is open for consultation until August 2021.

This proposal, published in Q1 of 2021, is often referred to as the AI Act. It is estimated to have an impact on the functioning of the health sector. The Commission considers the necessity of specifying additional sectoral policies complementary to a horizontal AI framework.

The act itself makes specific reference to the EHDS in light of machine learning techniques. For the development of so-called high-risk AI systems, constituting a high risk for the fundamental rights of citizens and the main target of the legislative initiative, high-quality data sets are vital. Such datasets are partly provided by the establishment of the nine common EU data spaces.

The EHDS might facilitate non-discriminatory access to health data to facilitate the training of AI algorithms while taking citizen rights in light of the GDPR, such as privacy, transparency, and security into account sufficiently.

## 4 Commonalities of governance

Governance is the act of governing an entity, where the entity territorially, politically, or issue-dependently, is demarcated by rule-set boundaries.

Authorities governing the entity can be categorised using a typology, defined as a classification of a set of ideal-type concepts which give insight into real-life phenomena that “reveals the hidden meanings and significance of the phenomena, suggesting what [...] important hypotheses ought to be concerned”<sup>5</sup>(Lowi 1972: 299).

This section elaborates on such ideal-type concepts, giving a non-exhaustive set of commonalities by which governing bodies regulating the secondary use of health data might be categorised.

### *Regulatory intensity*

The first commonality is the regulatory intensity by which the governing body operates, referred to as regulatory instruments.

A distinction is often made between classic command-and-control governing principles and novel forms of network governance. The former refers to top-down decision making from one centrally operating actor with binding rules and punishment in light of non-compliance for those active on the demarcated entity, eg. the draconian measure of financial penalties as the final step of an infringement procedure in EU law.

This is the historical conception of state governing, in transformation due to the increased usage of novel modes of co-production, a system in which policies are more inclusively formulated and iteratively revisable in light of contextual circumstances (De Búrca & Craig 2015: 163-165). These novel systems are based on network governance<sup>6</sup>, loose systems of not necessarily state actors in which generated rules often have a non-binding character: sharing of good practices, benchmarking, voluntary certification schemes, naming-and-shaming in light of comparative reporting.

Such schemes are particularly prominent in areas of shared legislative competencies in the multi-levelled European regulatory space as network governance is often considered in salient policy areas with conflicting views and interests, albeit not exclusive or exhaustive to these areas.

There is a third category of regulatory intensity, operating on rational actor principles on financial incentive structures. In contrast to command-and-control principles, the figurative whip, and different from purely voluntaristic governance, actor compliance gets achieved through positive and negative incentives: the carrot.

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<sup>5</sup> Lowi, T.A. (1972). “Four systems of policy, politics and choice.” *Public Administration Review*, 32: 298-310.

<sup>6</sup> Búrca, G. de & Craig, P. (2015). *EU Law: Text, Cases, and Materials*. Oxford: Oxford University Press.

### *Level of centralisation*

Related to regulatory intensity is the level of centralization on which the governing body operates, the second commonality.

A distinction can be made between bodies operating on the regional, national, and supranational level. With regards to health data, a Member State with a centralised system has bodies operating on the national level, such as Findata, the French Health Data Hub, the Danish Health Data Authority, or most types of health data are governed by one ministry, as identified in the 2020 OECD survey on health data governance (OECD, 2020: 48-53).

On the other hand, a Member State with a decentralised system might have no national permit body or centrally organised health data authority, having multiple entry points depending on the type of health data under discussion, with the Netherlands as a good case in point (idem 52). The supranational level would refer to governing bodies operating beyond national borders, strictly speaking, state actors not being the primary subject, in contrast to the international level, but instead one of the objects of governance, eg. recommendations on medicines from the EMA, advice on communicable diseases from the ECDC, parts of the mandate of the envisioned Health Emergency Preparedness and Response Authority (HERA), or even the functioning of the Commission itself.

### *Regulatory autonomy*

The third commonality is the regulatory autonomy of the governing body from other actors, notably the Member State or Commission, most aptly conceptualised in the literature on agency creation.

In classic principal-agent theories, the process of delegation refers to the transfer of powers or decision-making competencies from a principal towards an agent<sup>7</sup> (Dehousse 2016: 59). Such inter-organizational relations are defined in hierarchical terms. The principal should exercise control over the agent, hence is tasked with defining clear contractual boundaries to the agent's conduct in the attempt to reduce so-called political drift. Yet, lacking sufficient independence could lead to political capture, encroaching upon the very essence of the agency, ie. constantly providing technical output whilst not being too tampered by the irregularities of politics. At the same time, some influence ought to be expected as it intensifies channels for democratic legitimacy or inclusive participation through, for example, the management board including the Member States and the European Parliament or external stakeholder participation in an advisory forum, the case with EMA, ECDC, or the US-based Biomedical Advanced Research and Development Authority (BARDA).

### *Legislative intensity*

The fourth commonality relates to the organizational design, dependent on the intensity level of the legislative measure on which the mandate of the governing body is based.

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<sup>7</sup> Dehousse, R. (2016a). "The Politics of Delegation in the European Union." In: Ritleng, D. (eds.) Independence and Legitimacy in the Institutional System of the European Union. Oxford: Oxford Scholarship Online.

In chapter 5 each mechanism is categorized by one of the three intensity levels: low, middle, and high. The distinction between levels is neither black/white nor a trichotomy, rather a continuum.

They are explained as follows:

Level	Description
<b>Low</b>	<p>The low intensity mechanism is not be set up by an EU legislative act. It may be time-limited and the budget is fixed to the operating term. These mechanisms are most likely projects or temporary expert groups.</p> <p>Examples: High-level expert group on AI (HLEG on AI), Population Health Information Research Infrastructure (PHIRI project)</p>
<b>Middle</b>	<p>The middle intensity mechanism is established in EU law or a policy process at Member States level but they have no delegated powers or responsibilities to contribute to application of EU law. Most of these mechanisms are permanent expert groups or voluntary networks, reflecting the Open Method of Coordination (OMC).</p> <p>Examples: eHealth network (set up in a Directive), Data Innovation Board (to be set up in a Regulation), 1+ Million Genomes initiative (Member States joining through a ministerial declaration)</p>
<b>High</b>	<p>The high intensity mechanisms are always directly set up in EU law and have a clear mandate and responsibilities. They may have a legal personality. Regulations and directives are key tools in this category.</p> <p>Examples: European Data Protection Board, European Medicines Agency</p>

*Institutional constellation*

Closely related is the fifth commonality, the institutional constellation of the regulatory body.

Relevant factors might be the ways in which decisions are made, who is part of the management board (and who is not), what type of other advisory forums or committees are an institutionalised part of the organisations, and who are able to participate in these (and who are not). In a more normative and abstract sense, the answers to these questions touch upon the so-called input legitimacy of the governing body, the notion that those being ruled should have the ability to influence the process of decision-making (Risse & Kleine 2007: 72).

The secondary use of health data being a special case of health data governance and the notion that governing bodies are often far removed from the democratic process makes a discussion on input legitimacy salient. Thus, input legitimacy consists of two logics: internal and external accountability. As the terminology suggests, internal accountability refers to appropriate mechanisms within the organisation and external accountability to mechanisms

linking the governing body to the wider regulatory space, such as the relationship with external stakeholders<sup>8</sup> (Gulbrandsen & Auld 2016: 44-45).

*What is being governed*

The last commonality refers to the broader question of: what is being governed? Or phrased more specifically: what is the scope of EHDS governance? With regards to the secondary use of health data, three elements are of particular importance.

First, what type of health data is included or excluded in the mandate, differences between national health bodies identified in the publication on the implementation of the GDPR<sup>9</sup> and the OECD publication on health governance (OECD, 2020: 48-53).

The second issue is what is the scope and types of services the EHDS should provide. For example, its services could range from data discoverability only, to data discoverability and accessibility, or even to discoverability, accessibility and analysis of the data in a safe environment to answer a specific research question.

Third, is the body a central permit authority dealing with data requests, or rather a health authority operating beyond the Member States, a data intermediary in light of the DGA, a third-party coordination centre like DARWIN, a federated cloud as identified in the Inception Impact Assessment on the ECDC, or a body certifying data-parties linked to the DGA. Or would it be a network on the harmonization of data practices through sharing of best practice or creation of guidelines like the eHealth Network or the proposed functioning of the Data Innovation Board?

Depending on the answer to these fundamental questions, we can expect the role of any governing body to change substantially, and strongly influencing views on an ideal-type institutional constellation or the pros and cons of currently active governing mechanisms.

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<sup>8</sup> Gulbrandsen, L., & Auld, G. (2016). "Contested accountability logics in evolving nonstate certification for fisheries sustainability." *Global Environmental Politics*, 16: 42-60.

<sup>9</sup> Hansen, J. et al. (2021). *Assessment of the EU Member States' rules on health data in the light of GDPR*. Luxembourg: European Union, 2021. P 107

## 5 Who could govern health data for secondary use and how?

This chapter describes key elements of several existing and proposed mechanisms governing health data for secondary use.

For each mechanism, a table presents an overview, which describes the advantages and disadvantages, and potential impact of the successful governance. The table gives an assessment why the mechanism could work well in the health sector. The level of legislative intensity is assessed as low, middle or high using the scale described in the previous chapter.

The list of mechanisms discussed in the tables is not exhaustive, rather illustrating the multiplicity of on-going processes and possible models.

### *Mechanisms currently in operation*

1. Eurostat
2. EMA – HMA Joint Big Data Steering Group & DARWIN - pharmaceuticals
3. European Centre of Disease Prevention and Control – communicable diseases
4. eHealth Network, incl. National Digital Health Networks
5. European Reference Networks – rare diseases
6. At least 1 Million Genomes Initiative (1+MG) – genomic data

### *Proposals in the legislative process*

7. DGA Data Innovation Board
8. Health Technology Assessment

There are some mechanisms which, despite their importance, are not discussed in depth in this document but deserve a brief comment.

The **Joint Research Centre** (JRC) is the European Commission's science and knowledge service which employs scientists to carry out research in order to provide independent scientific advice and support to EU policies. JRC's work related to health sector includes many aspects of healthcare quality. JRC also work directly with health data in the development of a harmonized cancer information system for Europe and the European Platform on Rare Diseases Registration to provide a central access point for information on RD, improve access to patient registries, harmonise data and promote interoperability between registries.

**Horizon 2020** was the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness. The Horizon Europe programme continues the agenda with even bolder goals. EU innovation funding aims to ensure Europe produces world-class science, removes barriers to innovation and makes it easier for the public and private sectors to work together in delivering innovation.

In the health sector one good example of projects is PHIRI, the **Population Health Information Research Infrastructure**. PHIRI is a roll-out of the research infrastructure on population health information to facilitate and generate the best available evidence for research on health and well-being of populations as impacted by COVID-19. PHIRI has built

the Health Information Portal<sup>10</sup>, a one stop shop that facilitates the access to population health and healthcare data, information and expertise across Europe. PHIRI will allow for better coordinated European efforts across national and European stakeholders to generate the best COVID-19 population health knowledge. In doing so, PHIRI will lay the foundation to build a Distributed Infrastructure on Population Health (DIPoH) to be used to overcome future crisis and ensuring the sustainability of the project.

**Public-Private Partnerships** have significant role in EU. Put simply, a public-private partnership (PPP) is an arrangement between a public authority and a private partner designed to deliver a public infrastructure project and service under a long-term contract.

A prime example of such partnership is **the Innovative Medicines Initiative (IMI)**. It is the world's biggest public-private partnership in the life sciences. It brings together the European Union (represented by the Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations). One programme under IMI is the Big Data 4 Better Outcomes (BD4BO) programme which includes, among others, the EHDEN project (European Health Data and Evidence Network). Both are good examples how PPPs can facilitate the secondary use of health data.

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<sup>10</sup> <https://www.healthinformationportal.eu/>



## 6 Possible mechanisms in health data governance

### 6.1 Existing mechanisms

#### 6.1.1 Eurostat

<b>Mechanism</b>	1
<b>Mechanism name</b>	Eurostat
<b>Level</b>	High intensity (legal body / personality)
<p><b>Description</b></p> <p>Eurostat is one of the 33 Directorate Generals (DG) of the Commission. As the main statistical authority of the EU, it is broadly tasked with the development, production, and dissemination of EU statistics, further specified in <a href="#">regulation (EC) No 223/2009</a>.</p> <p>The DG publishes publicly available aggregated data free of charge on a vast array of topics, including health statistics. These comparative statistics cover the following issues in line with <a href="#">regulation (EC) No 1338/2008</a>: health status, health determinants, health care, disability, cause of death, health and safety at work (ec.europa.eu).</p> <p>Eurostat is likewise the Chair of the European Statistical System Committee (ESSC), a network of representatives from the national statistical institutes, who provide professional guidance on the functioning of the European Statistical System conform art. 7 of regulation 223/2009 through, for example, the endorsement of position papers. Such guidance is supposed to have a harmonising function by feeding into the development, production, and dissemination of EU statistics. The Committee is consulted by the Commission on issues related to European statistics in general, setting priorities regarding the European Statistical Programme, the annual working programme, issues concerning statistical confidentiality, and methodology related to the implementation of the European Statistical Programme. It meets three times a year.</p> <p>Moreover, Eurostat has a history in the production and dissemination of methodological publications in the attempt to harmonise practices and assist the Member States in carrying out the task of reporting data to the DG in a timely manner.</p> <p>The DG also has a longstanding working group, the WGPH, of national statistical officers on the public health statistics part of regulation 1338/2008, tasked with evaluating the decisions to be executed by Eurostat's health unit.</p>	
<p><b>Scope of this mechanism in the secondary use of health data</b></p> <p>As the statistical authority of the EU, the proliferation in the secondary use of health data could well fit within the mandate of Eurostat. The DG has a long history in data harmonisation and already aggregates health data from the Member States, albeit somewhat limited in scopes and often based on EU-wide surveys conducted in participating states, such as the European Health Interview Survey or the EU-SILC project on income and living conditions.</p> <p>Generally speaking, most surveys are not a form of using data for secondary purposes because the primary goal of a survey is to collect statistical data for scientific purposes with no reference to the provision of health or social care to a patient. In the case of health care, however, health surveys or health examination surveys are used in relation</p>	

to the treatment of the patient. Such data can likewise be linked to other datasets for additional analysis, which would be a secondary use of the relevant survey data.

Moreover, the DG partly functions as an EU-wide permit authority through the granting of access to confidential microdata restricted to scientific purposes. Any third-party institution, e.g. a university or statistical institute, must first be recognized as a research entity by Eurostat before applications on data access can be lodged. The assessment takes approximately four weeks and uses an eligibility framework: research should be the main activity or be part of a research department, evidence of publications should be provided, the institution has to be independent and autonomous in the formulation of scientific conclusions, and have adequate data safeguards. A list of recognised institutions is available online and has institutions from the EU, the Member States, and other countries. Afterwards, an application can be lodged using a research proposal, with Eurostat assessing the proposal's validity in consultation with the national statistical authorities. Aggregated data is publicly available and free of charge.

**Why this mechanism could work well in the health sector**

- Expertise in the production and dissemination of statistical data.
- Already partnered with national statistical institutions through the ESS Committee.
- Partnered with other EU stakeholders through the European Statistical Advisory Committee.
- Expertise in the harmonization of statistical data stemming from different parties.
- Expertise in the creation of codes of conduct and other documents which aim at intensifying the harmonization of practices between the Member States and other relevant parties.
- Relative independence in the setting of the organization's agenda.
- Method of quality evaluation and metadata setting in addition to elaborate quality checks and data assurance.
- Active in other statistical areas -> potentially curbing the issue of silos as a pitfall of other discussed mechanisms.
- Some experience as a permit authority on the secondary use of data.

**Why this mechanism would not work well in the health sector**

- Currently limited in scope with regards to processing of health data.
- Health data is currently a somewhat low priority of the DG, having relatively few staff members as a percentage of the total number of employees.
- Simultaneously tasked with other work not directly related to health data -> overburdened.
- Other relevant health data parties are not active within the ESS, thereby missing institutional ties to Eurostat.
- Envisioned tasks within the EHDS could fall outside of the organization's mandate-> additional legislation might be needed.
- Member States are not directly represented within Eurostat, in contrast to the institutional constellation of other European regulatory bodies, such as the management board of EU agencies. This might be problematic in light of the competencies of the Member States to organise the national health system.
- While the national statistical authorities represent the Member States in the board of the ESSC, not all authorities have health data set out as a field of expertise.
- Limited health-related expertise and no expertise in processing health data that is not traditionally considered as statistical data and treated differently, thereby falling outside of Eurostat's mandate

<ul style="list-style-type: none"> <li>- Inflexible compared to network governance. Reporting on health statistics is based on Regulation (EC) No 1338/2008 art. 2.</li> <li>- Data within the Eurostat system is anonymised and no further linkage between datasets can be made.</li> <li>- Eurostat sometimes lags behind schedule due to deficient data delivery from the Member States or deliberate quality checks and assurances, which does not fit the purpose when data is required rapidly.</li> </ul>
<p><b>Potential impact of successful governance</b></p> <ul style="list-style-type: none"> <li>- In the future, Eurostat could leverage its expertise in producing methodological reports in the newly created area of secondary health data, providing tools that might amplify the sharing of health data for secondary purposes between the Member States. Eurostat could likewise canalize its expertise with the creation of comparative data reports, using the newly acquired data through the EHDS to make EU-level comparisons on health-related subjects. In that sense, Eurostat could be envisioned as a user of the product, or an institutionalised pillar within the EHDS, profiting from novel avenues of data-sharing between the Member States. The latter notion is, however, somewhat different from the role of a regulating body, i.e. a user of the data as opposed to a provider.</li> </ul>
<p><b>Sources</b></p> <p><a href="#">Data - Health - Eurostat (europa.eu)</a>  <a href="#">EUR-Lex - 32009R0223 - EN - EUR-Lex (europa.eu)</a>  <a href="#">EUR-Lex - 32019L1024 - EN - EUR-Lex (europa.eu)</a></p>

6.1.2 EMA – HMA joint Big Data Steering Group & DARWIN EU

<b>Mechanism</b>	<b>2</b>
<b>Mechanism name</b>	EMA – HMA Big Data Steering Group & DARWIN EU
<b>Level</b>	BDSG: middle (permanent expert group; execution of HMA and EMA mandates, network governance) DARWIN: Low (project);
<p><b>Description</b></p> <p><b>The EMA-HMA Big Data Steering Group (BDSG)</b> has a mandate by the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) since December 2019 to advise to and execute on behalf of HMA and EMA Management Board.</p> <p>Members of the BDSG are representatives from the following organisations: EMA and HMA (co-chairmanship), National Competent Authorities, European Commission (DG Sante), eHealth Network, EU Innovation Network, EU Network telematics governance, EMA Committee for Medicinal Products for Human Use (CHMP), EMA Committee for Medicinal Products for Veterinary Use (CVMP), Pharmacovigilance Risk Assessment Committee (PRAC), EMA Scientific Advice Working Party, EU patient associations, EU health care professionals association.</p>	

BDSG receives organizational and administrative support by EMA.

**Data Analysis and Real-World Interrogation Network (DARWIN EU)** is a project in line with the tasks of BDSG. It aims to build a network of data, expertise and services with distributed data access, not a centralized database. The structure of DARWIN will be a federated network with a third-party coordination centre.

DARWIN is supported by EU policy initiatives, such as the EC Digital and Data strategies, the European Health Data Space (EHDS) and the EU Network Strategy to 2025.

The timeline of DARWIN foresees an establishment and piloting phase through 2021-2022 with the operational phase starting in 2023.

DARWIN is based on an explicit legal basis for access to and analysis of healthcare data in medicines regulation. This is not the case for all medicines regulatory processes.

The project will act as a pathfinder initiative and use case for the EHDS.

Next steps in the project include firstly the implementation of an Advisory Board to advise on the further setup of DARWIN and which is to be headed by an EMA representative and the German regulatory agency (Federal Institute for Drugs and Medical Devices). Secondly, a call to establish a coordination centre has been launched.

The coordination centre will operate the technological and methodological services for the provision of access to data and execute scientific studies. Establishing connectivity to the EHDS is specifically asked for in the call. The coordination centre is described as a “key user” of the EHDS as it is supposed to provide “a strong system of data governance, rules for data exchange and data quality, strong infrastructure and interoperability and a connection to the EHDS network of Data Permit Authorities and Nodes.” Technical and organisational measures of the EHDS act need to be taken into account in the setup of the coordination centre.

### **Scope of this mechanism in the secondary use of health data**

The focus of both BDSG and DARWIN is on the regulation of human and veterinary medicines in the EU. It is, however, planned to open the network to other uses such as policy making, healthcare delivery and health technology assessment.

BDSG and DARWIN are both data providers, which establish governance rules for data access, and data users, whose needs have to be taken into account in the EHDS regulation. Roles (data controller vs. data processor) are not strictly separable in this case. This double function needs to be taken into account in the assessment.

The main scope of the BDSG is joint HMA/EMA Big Data Steering Group is to advise the EMA Management Board and HMA on prioritisation and planning of actions to implement the ten priority recommendations in the Big Data Task Force final report.

It is also responsible amongst others to monitor advances in the science, technology, legislation, and regulation of Big Data to identify opportunities and threats and make recommendations to HMA and EMA.

Finally it aims to ensure coordination and alignment towards goals with the Commission (including flagship policy initiatives such as Europe’s Beating Cancer Plan and the EHDS), HMA and EMA on any ongoing or new initiatives.

Tasks of the BDSG are:

- Delivery of a sustainable platform to access and analyse healthcare data from across the EU (= DARWIN)
- Establishment of an EU framework for data quality and representativeness
- Enabling data discoverability
- Development of EU Network skills in Big Data
- Strengthening EU Network processes for Big Data submissions
- Building EU Network capability to analyse Big Data
- Modernising the delivery of expert advice
- Ensuring data are managed and analysed within a secure and ethical governance framework
- Collaboration with international initiatives on Big Data
- Creation of an EU Big Data ‘stakeholder implementation forum’

The scope of DARWIN is the **access to and analysis of real-world data** to complement evidence from randomised clinical trials and support the development, authorisation and supervision of medicines along the life cycle.

#### **Why this mechanism could work well in the health sector**

- BDSG might work well in the health sector as it already has a wide representation of public stakeholders from the health sector. The working structure is established based on clear mandate.
- The group has a wide spectrum of tasks with links to secondary use of health data. The focus is on ‘Big Data’, which includes primary and secondary use of data.
- DARWIN will establish a platform to access and analyse RWE data, which can be a best practice model for secondary use of health data for the EHDS.

#### **Why this mechanism would not work well in the health sector**

- Both BDSG and DARWIN have, with regards to governance, a narrow focus on the regulation of medicines. Even though BDSG has a clear mandate for governance autonomy, this is limited to data use for regulatory purposes. BDSG / DARWIN might eventually be an important building block of the EHDS (as a data provider) and the governance of data use in medicines regulation. BDSG / DARWIN will, however, likely not be able to provide overarching governance for the whole health sector.
- The definition of the governance structure of DARWIN is being done in parallel to the EHDS act; it is therefore unclear yet who will look to whom for guidance. The proposal on revamping the mandate of the EMA includes links to the EHDS, even though the role as data controller or processor is still unclear (see Chapter 3 - Building a European Health Union).
- The EHDS legal act will likely establish a permanent governance, whereas DARWIN might be a project with limited time. Also, funding of DARWIN after 2023 is yet to be established (impact assessment on financing from EMA fees ongoing), which confirms the project status of DARWIN.

#### **Potential impact of successful governance**

- The governance for a federated infrastructure of DARWIN EU might act as a blueprint for the EHDS governance (depending on the timeline of DARWIN).
- The established forum of the BDSG can be a building block of the EHDS for medicines regulation.

<ul style="list-style-type: none"> <li>- Following guidance from the Data Governance Act on the structure of the Data Innovation Board, representation of the BDSG in the Data Innovation Board in an expert role can be discussed.</li> <li>- Opening of DARWIN to EU nodes / data permit authorities with a wider scope than regulation of medicines might have huge potential to link data of regulatory agencies with data from public health, policy planning, research etc.</li> </ul>
<p><b>Sources</b></p> <p>Steering Group Mandate: <a href="https://www.ema.europa.eu/en/documents/other/mandate-hma/ema-joint-big-data-steering-group_en.pdf">https://www.ema.europa.eu/en/documents/other/mandate-hma/ema-joint-big-data-steering-group_en.pdf</a></p> <p>Report: <a href="https://www.ema.europa.eu/en/documents/report/big-data-steering-group-bdsg-2020-report_en.pdf">https://www.ema.europa.eu/en/documents/report/big-data-steering-group-bdsg-2020-report_en.pdf</a></p> <p>DARWIN: <a href="https://www.ema.europa.eu/en/documents/presentation/presentation-big-data-steering-group-bdsg-workplan-update-darwin-eu-implementation-approach_en.pdf">https://www.ema.europa.eu/en/documents/presentation/presentation-big-data-steering-group-bdsg-workplan-update-darwin-eu-implementation-approach_en.pdf</a></p> <p>DARWIN Coordination Center Call: <a href="https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8503">https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8503</a></p>

### 6.1.3 European Centre of Disease prevention and Control

<b>Mechanism</b>	<b>3</b>
<b>Mechanism name</b>	European Centre of Disease prevention and Control
<b>Level</b>	High intensity (legal body / personality)
<p><b>Description</b></p> <p>The ECDC is tasked with identifying, assessing, and communicating current and emerging human health threats stemming from communicable diseases, its mandate further specified in <a href="#">Regulation 851/2004</a>. The agency has the following tasks: collecting data; producing reports, such as the Annual Epidemiological Report; training health officials; administering the journal Eurosurveillance; offering scientific advice on own initiative or at request; and health surveillance as part of the EWRS.</p> <p>The last task in particular deals with health data by functioning as a web-based system with restricted access connecting the agency to the Commission and public health authorities responsible for communicable diseases in the Member States and the EEA countries. During the Covid-19 pandemic, confirmed cases are reported every 24 hours, data feeding into the publicly available sources, such as Rapid Risk Assessments, weekly surveillance, and country overview reports.</p> <p>In that sense, the ECDC is a central node in a broader network of scientific information on communicable diseases, collecting data from the Member States and integrating them into publicly available reports or datasets with restricted access. The Commission envisions expanding the agency's tasks as part of the broader legislative package on strengthening the preparedness of the EU in light of the current pandemic.</p>	

The agency has a unit on data and digital governance called DTS and will launch two novel platforms in 2021 on surveillance, data-sharing, and communication, called EpiPulse and ETMS.

**Scope of this mechanism in the secondary use of health data**

The ECDC is active in the area of secondary health data, be it restricted to communicable diseases. This is defined in article 11 of the ECDC founding regulation, which stipulates the task of collecting and analysing data on the Community level (Regulation 851/2004: art. 11(1)). The article further specifies the responsibility of developing appropriate procedures to facilitate data transmission between the Member States and the Commission, a task striking at the very heart of an EU body governing the envisioned EHDS (Idem: art. 11(2)).

Being a central node, the agency was able to integrate diverging data systems on disease surveillance into one homogeneous system, the TESSy. Conform article 4a of the ECDC regulation, the Member States are obliged to provide information to the system in a timely manner, i.e. once every week, the confidential data accessible to a restricted number officials: individuals nominated by Member States or EEA countries, the European Commission, relevant EU bodies, relevant international organisations, in line with an official nominating procedure. Regarding international organisations, direct or case-by-case access may be granted whenever such access is necessary to serve the public interest and safety of the EU. A meta data report on TESSy data is publicly available via the ECDC website.

Subsets of the collected data can be accessed for scientific purposes by third parties, such as academic institutions, universities, and NGOs, notwithstanding restrictions in line with article 4 of regulation 1049/2001 on access to public documents from EU institutions, which limits accessibility on the grounds that disclosure might undermine the public interest. The ECDC acts as a permit authority, tasked with assessing the data access applications on a case-by-case basis and obliged to justify the reasoning for the non-disclosure of datasets. Any application gets accompanied by a notification to the Member States whose data is part of the extraction, able to object to the extraction with reference to regulation 1049/2001. The ECDC, however, has the final say on the request and will take the Member State’s opinions into account. TESSy has a working group composed of national experts nominated by the Member States. Aggregated is likewise available for secondary purposes through the Surveillance Atlas of Infectious Diseases, the Annual Epidemiological Report, and other relevant publications.

The ECDC also administers a central database on WGS and interoperable with an EFSA database on microbial typing and available to the Member States since April 2020.

**Why this mechanism could work well in the health sector**

- Legal personality as an EU agency.
- Relative independence in setting of agenda.
- Member States are directly represented within the Management Board. This increases internal accountability, amplified by inclusion of the European Commission and the Parliament.
- Other third parties are active through the Advisory Forum, providing external accountability.
- Medical expertise.

<ul style="list-style-type: none"> <li>- Ties with national competent bodies.</li> <li>- Expertise in the production, development, and dissemination of statistical health data on communicable diseases at the community level.</li> <li>- Able to give advice on own initiative or at request.</li> <li>- Recent success in harmonising databases through the workings of the TESSy, likewise having a link to the secondary use of health data.</li> <li>- Limited competence as a permit authority on data requests.</li> </ul>
<p><b>Why this mechanism would not work well in the health sector</b></p> <ul style="list-style-type: none"> <li>- Mandate is limited to efforts regarding communicable diseases -&gt; lack of legal basis for other health-related activities.</li> <li>- This might likewise foster the creation of a siloed approach in the area of health data.</li> <li>- Already new legislation under discussion with limited ties to the EHDS and no link with non-communicable diseases. Problematic in light of the aforementioned.</li> </ul>
<p><b>Potential impact of successful governance</b></p> <ul style="list-style-type: none"> <li>- The ECDC could use its expertise in harmonizing data to intensify the efforts of the Member States to share health data for secondary purposes. This view should consider the limited scope of communicable diseases in line with the agency's mandate.</li> <li>- Moreover, the ECDC could use novel forms of secondary data acquired through to EDHS framework to create cross-border health reports. These are not just able to compare the (best) practices of Member states but could also feed into the broader scientific community.</li> <li>- Most relevant in light of the current Covid-19 crisis and the efforts to augment the agency's mandate. In this scenario, the agency would likewise become a user of the product, as opposed to solely being a provider of health data services.</li> </ul>
<p><b>Sources</b></p> <p><a href="https://ec.europa.eu/eurostat/tgm/table.do?tab=table&amp;init=1&amp;language=en&amp;code=sdg_3_6_2">Data - Health - Eurostat (europa.eu)</a>  <a href="https://eur-lex.europa.eu/eli/reg/2020/1023/oj">EUR-Lex - 32009R0223 - EN - EUR-Lex (europa.eu)</a>  <a href="https://eur-lex.europa.eu/eli/reg/2020/1049/oj">EUR-Lex - 32001R1049 - EN - EUR-Lex (europa.eu)</a></p>

#### 6.1.4 The eHealth Network

<b>Mechanism</b>	<b>4</b>
<b>Mechanism name</b>	EU body governing the secondary use of data: the case of the eHealth Network
<b>Level</b>	Medium
<p><b>Description</b></p> <p>The eHealth Network is originally set up under Directive 2011/24/EU on patients' rights in cross-border healthcare and connects national authorities responsible for eHealth.</p> <p>The objectives of the eHealth network are (Directive 2011/24/EU, Article 14) to:</p>	



- a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare.
- b) draw up guidelines on a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and
- c) draw up guidelines on effective methods for enabling the use of medical information for public health and research;
- d) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

Through this voluntary e-Health Network, EU countries can give direction to eHealth developments in Europe and help shape policy on eHealth interoperability and standardisation.

The eHealth Network has elaborate rules of procedures, specifying a multiannual work program, and it consists of multiple subgroups, allowing for in depth elaboration and preparation of topics, such as subgroups on mHealth, interoperability, semantics and legal questions.

#### **Scope of this mechanism in the secondary use of health data**

The eHealth Network's scope is to draw up guidelines on effective methods for enabling the use of medical information for public health and research. This scope can be declared applicable to secondary use of health data as well.

The eHealth Network could draw on the expertise available in all of the eHealth Network subgroups – legal, semantics and interoperability. Health data governance in this mechanism then would come down to making arrangements and agreements on different levels (or layers, ReEIF 2015), supported by new EU legislation (DGA/GDPR).

#### **Why this mechanism could work well in the health sector**

- Fully covers the EU members states
- Offers the option of developing a broad support base among member states
- The eHealth Network is already functional; and has proven its value earlier on several important topics such as COVID-19, cross-border health care, the patient summary, and others.
- Additionally, with the better regulation initiative as a catalyst for the revision of article 14 of Directive 2011/24/EU, the eHealth Network has been advised by the eHAction Joint Action to enhance interoperability for cross-border health data exchange through the inception of National Digital Health Networks (NDHN) and a Joint Coordination Process (JCP). To facilitate implementation of the NDHN the eHAction recommends, according to national competence, needs and strategies, to:
  1. Identify the possible interdependences between the nodes of NDHN (National Action).
  2. Identify similar nodes in the NDHN among the different Member States (EU Cooperation).
  3. Promote better procedural coordination.

**Why this mechanism would not work well in the health sector**

- The eHealth Network has limited legal status / decisions have no obligatory status
- In its current form the eHealth Network has no formal representation of EU institutions such as Eurostat, ECDC and others, because they are integral part of the EU; involvement of these and perhaps other stakeholders would be crucial for secondary use of health data.
- At present the work within the eHealth Network can be described as voluntarily aligning elements of national health policies, with an emphasis to have the European citizen benefit of this work. As a governing mechanism therefore, the eHealth Network could attain at best 'only' alignment of policy relating to all national health data governance infrastructures.
- Implementation of the NDHN is not yet realized in (all) member states.

**Potential impact of successful governance**

- If the eHealth Network governs the use of both primary and secondary use of data, it can illicit unforeseen synergies. The eHealth Network already sets the conditions for (increased) interoperability by agreeing which standards (technical, semantic) to use. It can be regarded as another step towards a more unified and accessible Europe in the context of (re-use of) health data.
- The development of a common frame of reference to which all partners in the EU Digital Health ecosystem can refer to when they think and act vis-à-vis national level topics regarding eHealth through the NDHN and JCP would offer great opportunities for policy harmonization.
- The establishment of bodies or functions relevant to the development of a fruitful national eHealth ecosystem, if these do not already exist.

**Sources**

Directive 2011/24/EU, Article 14.  
 European Commission (2021). eHealth : Digital health and care.  
[https://ec.europa.eu/health/ehealth/cooperation\\_en](https://ec.europa.eu/health/ehealth/cooperation_en)  
 eHealth Network (2015). Refined eHealth European Interoperability Framework.  
[https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev\\_20151123\\_co03\\_en.pdf](https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20151123_co03_en.pdf)  
 eHealth Network [Recommendation](#) for the Development of National Digital Health Networks in the EU Member States (WP1 – draft for adoption)

6.1.5 European Reference Networks

<b>Mechanism</b>	<b>5</b>
<b>Mechanism name</b>	European Reference Networks
<b>Level</b>	Medium
<b>Legal base</b>	Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
<b>Description</b>	

The European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate clinical treatment of complex or rare diseases and conditions that require highly specialised treatment, concentrated knowledge and resources, not necessarily available in all countries. The first ERNs were launched in 2017 and they currently involve more than 900 highly specialised healthcare units from over 300 hospitals in 26 EU countries. There are 24 thematic ERNs, which work on a range of disease groups but the expansion of the networks has been in process since 2018.

The work of the ERNs is led by the Board of Member States, set up in the Directive 2011/24/EU. The Board is composed of a representative from all the Member States. This policy level coordination is complemented by the ERN Coordinators Group (ERN-CG). The Group develops common strategies, guidelines and procedures in areas such as research, knowledge generation, and data sharing. The role of the ERN Coordinator is defined in the implementing decision 2019/1269. The ERN Coordinator is appointed by the Network and lead its day-to-day work and represents the thematic Network.

The ERNs handle pseudonymised clinical patient data in their primary function but develop and collect data in registries of rare diseases for secondary use. For their primary function, the ERNs use a secure, collaborative platform, called Clinical Patient Management System (CPMS). Most ERNs have established registries, funded from the EU Health Programme.

#### **Scope of this mechanism in the secondary use of health data**

ERNs focus on rare diseases where the secondary analysis has an additional value.

The common consent for the patients enrolled and benefitting the clinical assessment is uniform for all ERNs and explicitly mentions the secondary use.

Further common procedures for ERN registries could streamline access to data, have a secure cloud to store their registries and simplify registry implementation, receive access to tools for analytics and the use of AI.

The ERNs provide a model for cross-border primary and secondary use of health data in a highly specific case.

#### **Why this mechanism could work well in the health sector**

- Specifically designed for a medical issue and supported by a professionally competent group of actors.
- Combination of policy-led governance (Board of Member States) and professional governance (the Coordinators Group).
- Supported by primary and secondary law (Directive and implementing decisions)
- Strong stakeholder support

#### **Why this mechanism would not work well in the health sector**

- Lack of policy ambition in the cross-border governance
- Lack of support and funding from Member States due to the close link to the management and funding of the national healthcare system
- Lack of funding at EU level to support cross-border exchange of data

<ul style="list-style-type: none"> <li>- Differences in opinion between policy makers responsible for national systems and highly qualified professionals treating patients</li> <li>- Difficulty to produce common semantic and interoperable infrastructures due to wildly differing needs of very diverse diseases.</li> </ul>
<p><b>Potential impact of successful governance</b></p> <ul style="list-style-type: none"> <li>- The Networks have a high potential to benefit patients with rare diseases in diagnosis and treatment, improve understanding of the biological mechanisms behind the disease, especially for ultra-rare diseases</li> <li>- ERNs provide a model for data governance in a specific sector</li> <li>- A model to reduce costs for the healthcare systems through cross-border collaboration (e.g., reduced time to diagnosis)</li> <li>- A rare disease patient is not forced to travel to undergo a medical assessment and consultation to the best European standard</li> <li>- ERNs represent an unprecedented opportunity to build registries, produce guidelines, establish clinical pathways, and develop new diagnostics and therapies for rare disease.</li> </ul>
<p><b>Sources</b></p> <p><a href="https://ec.europa.eu/health/ern_en">https://ec.europa.eu/health/ern_en</a></p>

#### 6.1.6 1+ Million Genomes Initiative

<b>Mechanism</b>	<b>6</b>
<b>Mechanism name</b>	Special Group of “Signatories of the Declaration «Towards access to at least 1 million sequenced genomes in the EU by 2022»” (1+MG Group)
<b>Level</b>	Middle intensity
<b>Legal base</b>	Political declaration signed by Member States at ministerial level (2018)
<p><b>Description</b></p> <p>The 1+ Million Genomes (1+MG) initiative is an open policy cooperation mechanism of Member State. It involves 24 countries through signing of a Declaration at ministerial level. The initiative was launched on the EU Digital Day in 2018. The Declaration set a target to have at least 1 million sequenced genomes accessible across borders in the EU by 2022.</p> <p>The representatives of the signatory countries meet on a regular basis in a Special Group set up by the Commission to achieve the aim of the Declaration. The Special Group is supported by 12 Working Groups and a EU-funded support project Beyond 1 Million Genomes (B1MG, secretarial in the Elixir group).</p> <p>The Genome of Europe multi-country project will build a high-quality European network of national genomic reference cohorts, representative of the European population.</p>	

Further EU funding is planned for building further data governance and the necessary infrastructure.

**Scope of this mechanism in the secondary use of health data**

The signatory countries seek to set up an appropriate technical infrastructure across the EU allowing for secure, federated access to genomic data held nationally for healthcare, public health and research and innovation purposes. The access would be based on an agreed ethical and legal framework. In addition, the Signatories advance knowledge about genomics and promote its uptake by healthcare systems and integration into personalised healthcare. Ideally, the signatory countries would make genomic data, which is collected for any purpose, accessible across their borders. Much of this use will be, by definition, secondary use of genomic data.

**Why could this mechanism work well in the health sector?**

- The 1+MG initiative is designed to serve a specific need in the health sector for a specific category of health data, the genomic data.
- The initiative has been financially supported by the EU's programmes for digital transformation and is strongly supported by nearly all the Member States.
- The 1+MG initiative seeks not only to build a technical and semantic infrastructure but also develops the ethical, legal and societal elements (ELSI), which is prepared by a specific Working Group (WP5). The ambition level has not included developing EU legislation but using the existing laws.

**Why would this mechanism not work well in the health sector?**

- Setting up a separate mechanism of governance for each health data category and a related dedicated technical infrastructure could severely fragment the governance of health data.
- The new infrastructure could, if not properly coordinated, create a siloed technology to share health data.

**Potential impact of successful governance**

- The setting up a coordinated data governance mechanism for high-quality genomic data would result in an unprecedented access to genomic data across different populations in Europe. This would have direct benefits for research and personalised medical practice and further positive impacts on prevention, public health and healthcare.
- A successful governance of "a Genomic Data Space" (GDS) would ensure the close links of the genomic data management to other specific health data management systems under the umbrella of the European Health Data Space.

**Sources**

[The 1+ Million Genomes initiative](#)

<https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>

[Roadmap 2020-2022](#)

[https://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=69606](https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=69606)

6.2 Proposed mechanisms

6.2.1 DGA European Data Innovation Board

<b>Mechanism</b>	<b>8</b>
<b>Mechanism name</b>	DGA European Data Innovation Board
<b>Level</b>	Middle (expert group no legal personality)
<b>Legal base</b>	Proposal for the Data Governance Act (Regulation)
<p><b>Description</b></p> <p>The European Data Innovation Board is proposed in Chapter VI (Art. 26 &amp; 27) of the draft of the Data Governance Act.</p> <p>This expert group is to be chaired by the Commission and will consist of representatives of the relevant authorities in the member states, representatives of the relevant data spaces and representatives of the relevant bodies in specific sectors.</p> <p>This structure could be expanded to create a specific governance mechanism for the health sector.</p>	
<p><b>Scope of this mechanism in the secondary use of health data</b></p> <p>The Board’s task is to “advise and assist” the Commission on developing a consistent practice for sharing data, on prioritisation of cross-sector standards and in enhancing the interoperability of data and data sharing services</p> <p>Its scope could be expanded by establishing a subgroup dedicated to the health sector. This potential subgroup could be tasked to advise and assist the Commission on setting standards and enhancing interoperability for the health sector in particular.</p> <p>Alternatively, a separate board for the health sector (Health Data Innovation Board) could be established under the EHDS for tasks mentioned above.</p> <p>Possible members of a dedicated board or a subgroup include representatives from the competent institutions and ministries of each Member State as well as experts for research and innovation in the health sector. Representatives of the health industry and patient representative organisations might also be included.</p>	
<p><b>Why this mechanism could work well in the health sector</b></p> <ul style="list-style-type: none"> <li>- Through this, the needs and specificities of data in the health sector could be discussed at an early stage.</li> </ul>	

<ul style="list-style-type: none"> <li>- The representatives from the competent institutions/ministries and experts for research and innovation in the health sector can give valuable insight to the Commission.</li> <li>- This would provide the Commission with information needed to make the best possible legislation, for example regarding the secondary use of health data.</li> </ul>
<p><b>Why this mechanism would not work well in the health sector</b></p> <ul style="list-style-type: none"> <li>- The Board (or an option based on DGA) lacks any executive power and has only an advisory function. For an autonomous data governance in the health sector, further governance mechanisms would be necessary.</li> <li>- Formation of a subgroup could lead to fragmentation of the Board’s work into different, sector-specific subgroups. Such a “silo-approach” would endanger the Board’s task to enhance interoperability and data sharing services between different sectors and domains.</li> <li>- If a dedicated board for the health sector were created, it would provide advice in the area of health data only, while the Data Innovation Board would be responsible for the interoperability between the different sectors. Beneficial cooperation of these two boards would have to be ensured.</li> </ul>
<p><b>Potential impact of successful governance</b></p> <ul style="list-style-type: none"> <li>- A distinct but not separate approach for the health sector and its specificities might enable more tailored solutions for legislation regarding the secondary use of health data.</li> <li>- Standardisation and interoperability in the health sector could be better supported.</li> <li>- At the same time, the Data Innovation Board could maintain the linkage to other sectors.</li> </ul>
<p><b>Sources</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767</a></p>

### 6.2.2 Governance for Health Technology Assessments

<b>Mechanism</b>	<b>9</b>
<b>Mechanism name</b>	Governance for Health Technology Assessments (HTA)
<b>Level</b>	High
<b>Legal base</b>	Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU
<p><b>Description</b></p> <p>Health Technology Assessment (HTA) is based on review of studies or uses existing data. HTA is a research-based tool to support decision-making in healthcare. HTA assesses the added value of new or existing health technologies – medicines, medical devices and diagnostic tools, surgical procedures, as well as measures for disease prevention, diagnosis or treatment – compared with other health technologies</p>	

The compromise proposal for the HTA would establish a Coordination Group, which would be composed of Member States' representatives, in particular from health technology assessment authorities and bodies. The members also designate their national or regional authorities and bodies as members of the subgroups.

The Coordination Group will be the group that performs joint clinical assessments and joint scientific consultations in order to ensure a Member State led approach. The Coordination Group will also carry out horizon scanning of new technologies.

The Coordination Group guides the HTA work, adopts the guidelines for conducting assessments and selecting assessors, and endorses the reports from the joint clinical assessments and scientific consultations.

**Scope of this mechanism in the secondary use of health data**

- The scope is limited to a specified secondary use case of health data
- Most HTAs are carried out on pharmaceuticals, and only a minor part on other medical technologies
- HTAs make only limited secondary use of data as most assessment reports are based on published studies

**Why this mechanism could work well in the health sector**

- The proposed mechanism responds to a specific healthcare need and establishes a tightly controlled procedure for the secondary use of data
- The governance is anchored in the competent authorities of Member States and their technically competent representatives.
- The Regulation would set up an EU-wide tool and coordinated by the Commission and the EMA to shed light on the evidence.

**Why this mechanism would not work well in the health sector**

- It is highly sectorial and may become rigid.
- If HTA experts are not involved early on and systematically in the design of the clinical trials used for marketing authorisation application, the clinical data collection would not respond to the needs of payers and HTA bodies when it comes to evaluating the socio-economic impact of a new health technology.
- The results of the process, led by the Member States, might get politically charged as they may be seen to influence the healthcare practice in Member States.

**Potential impact of successful governance**

- A clear legal basis (Regulation) ensures the long-term sustainability of HTA cooperation in the EU.
- Increases in the value of secondary data and showcasing of the importance of the use of data representing different formats.
- Demonstrates how to combine data from various sources and disciplines.
- Results in a reduction of the administrative burden, especially for smaller Member States and also companies, since the developers of health technologies should only have to submit information, data and other evidence required for the joint clinical assessment once at EU-level.
- Facilitates business predictability, reduce duplication of efforts for HTA bodies and industry.



**Sources**

<https://data.consilium.europa.eu/doc/document/ST-13636-2020-INIT/en/pdf>

<https://www.consilium.europa.eu/media/48963/st07310-en21.pdf>

<https://www.consilium.europa.eu/en/press/press-releases/2021/06/22/health-technology-assessment-informal-deal-between-council-and-european-parliament/>

## 7 Discussion of possible future governance mechanisms

There have been several suggestions and efforts over time to improve the access and use of health data across borders in the European Union. This is also the main objective of creating the European Health Data Space. A key element in this is to set up its governance through European legislation, ie. the forthcoming proposal for a Regulation on the EHDS. An important question in setting up the governance is its scope of tasks governing various stages in access to data: from data collection and access permits to safe processing, promotion of analysis and other use.

A network of national or regional health data access authorities could be building on existing authorities and agencies, such as Findata<sup>11</sup> and the French Health Data Hub<sup>12</sup>. These authorities have an important role in promoting or gatekeeping access to health data for secondary use.

In practically all European countries, national public health institutes are responsible for collecting national health data on health behaviours, health status and the use of healthcare. Their framework varies in regulation, policies and organisational structure. They collect data for their statutory tasks but also for international comparisons.

Some are central authorities like the Danish Health Data Authority and the Finnish Institute for Health and Welfare. In some countries there are several national stakeholders like National Health Insurance Funds in Estonia and France together with national health institutes. See the OECD working paper<sup>13</sup> on this topic. The institutes already work widely together in voluntary European projects. A more stable network based on EU law and better-defined cross-border responsibilities could bring these authorities closer to each other.

Health data sets are nationally or regionally defined, or they are used for administrative purposes that do not always match the needs of patients care or do not provide options to combine data from different sources, even nationally. Differences are all too obvious in the digitalisation and the digital use of electronic patient records.

In many European countries, there is already legislation for secondary use of health data, but in others there is an increasing interest to develop such legislation and governance models to link, combine, process and access the health data especially for public health purposes and policies and at the same time keep the high standard of privacy, security and safety.

National health data permit authorities, like Findata and Danish Health Data Authority, focus on gatekeeping and streamlining the access permit process. In France, the French Health Data Hub focuses on promoting the use of health data and linking of health data sets for research purposes, and it works with CNIL<sup>14</sup>, which is the French data permit authority. Also

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<sup>11</sup> <https://findata.fi>

<sup>12</sup> <https://www.health-data-hub.fr>

<sup>13</sup> Odekirk, J (2021), "Survey results: National health data infrastructure and governance", OECD Health Working Papers, No. 127, OECD Publishing, Paris, <https://doi.org/10.1787/55d24b5d-en>, page 48.

<sup>14</sup> Commission Nationale de l'Informatique et des Libertés, see <https://www.cnil.fr/en/home>

federated organisational solutions exist which should be taken into account in the governance of European network.

All these data access organisations are experienced in secure and privacy conscious data use and have an increasing capacity and knowledge of possibilities for the secondary use of health data: where the data lies, how it can be blocked, combined, anonymised, pseudonymised, aggregated and processed in the safe and secure environment. They are also aware of pros and cons of the validity of the data to be used.

Setting up a new European-level network could speed up the founding of national or regional health data access authorities. A network would promote the exchange of experience and good practices, peer learning, benchmarking and open dialog. Such a network could also support the European Health Data Space in developing European governance. National nodes could lead to implementing Article 7 of the proposed Data Governance Act, which suggests setting up a model for national single points of contact.

This networking could work well in the health sector because the network members would benefit from others' experience, some institutes are already networking on a voluntary basis<sup>15</sup>. It would facilitate solving problems of health data permit and access authorities by knowing the needs of the users of health data in secondary use.

A network is a low-cost solution which is legally and regulatory easy to accept and start. It could combine diverse elements from different countries if its scope is defined widely. Further, it could be easily connected to an existing EU structure.

To be successful, the network would need to combine diverse types of health data from genomes and biodata to health service and well-being data. The network would need to ensure common rules to avoid regime shopping. Currently, national or regional institutes cover only part of the health data and the level of their digitalisation varies.

The network's task could include developing cross-border data permit process, combination of data sets, definition of the priority data sets, as well as techniques for pseudonymisation, anonymisation and aggregation. Finally, the network could define standards for safe access and secure processing environment. EU-level standards would better guarantee the privacy and create trust in processing sensitive health data for defined purposes.

Challenges arise from the fact that some authorities are working on collecting data, others promoting its use and others largely working on data access permits. Some of them already exist but some countries are only contemplating setting them up. The network would need to combine both existing and new players and not just national but also regional health data access authorities.

Despite the long tradition of cooperation in health data collection, quality of the data and the semantics used vary between and within countries. Availability of data varies, and it takes long time to get the data. This is a crucial problem to overcome when digitalisation and

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<sup>15</sup> The International Association of National Public Health Institutes (IANPHI) collectively builds public health capacity and capabilities by connecting, developing and strengthening national public health institutes worldwide. <https://www.ianphi.org/index.html>

options to have health data almost in real-time are becoming a norm. Furthermore, data formats need to enable use of better analytics tools and AI.

Another option to govern the use of health data in the EU would be to set up a new EU agency, an EU Health Data Agency. The new agency would have more operational capacity than a network and it would likely cover both primary and secondary use, which both are in the scope of the EHDS. Therefore, it could cover the current EU initiatives to exchange primary health data across borders, including exchange of prescriptions and patient summaries through MyHealth@EU and clinical data in the European Reference Networks. Such tasks are better managed by an agency than as currently by a policy making department of the Commission (DG Sante).

For the secondary use the health data agency would need to have a mandate to coordinate the interdependencies between health data mechanisms described in this document and to carry out new responsibilities regarding data access, which will be established by the EHDS Regulation. As “an operative arm” of EU health data policies, the health data agency would need to work closely with other health-related agencies, such EMA and ECDC, or be their extension.

Furthermore, the role of stakeholders will need to be defined so that this governance model and service is client-oriented to satisfy the needs of different user groups, and to promote trust in citizens.

The benefits of a common European framework for the use of secondary health data obtained from different EU countries and regions would greatly promote health research, health policy making as well as innovation in Europe. It would advance harmonisation and quality of health data, expand exchange of health information through strengthened European level coordination. Health data economy is a fast-growing business sector in need of more effective governance.