Deliverable 5.4

Options for governance models for the European Health Data Space

17 January 2023

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

0 Document info

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0.2. Keywords

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

Accepted in Project Steering Group on 25 October 2022. The European Commission gives final approval to all joint action's deliverables.

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Executive summary

The present document develops well-established options for governance of the European Health Data Space (EHDS), taking into account a European perspective and the best interest of stakeholders and citizens. It argues that EHDS governance should be based on clearly defined roles for the actors that will process personal data, in accordance with the General data Protection Regulation (GDPR). Relevant groups for the EHDS are: (i) data subjects; (ii) data controllers; (iii) data processors; (iv) and bodies governed by public law.

The document further assessed underlying principles for the drafting of legislation on governance – both nationally and internationally – drawing on ethical principles for digital health. With the following four overarching principles, they aspire to foster shared understanding and inclusive implementation of the EHDS: (i) base digital health on humanistic values; (ii) enable individuals to manage their digital health and data; (iii) make digital health inclusive; (iv) and implement eco-responsible digital health.

The document then underpinned the discussion on EHDS governance using the European Interoperability Framework. This framework consists of four layers of interoperability: (i) legal; (ii) organisational; (iii) semantic; (iv) and technical. For legal interoperability, the Data Lifecycle was introduced to give a full picture of EHDS governance options. The other interoperability layers draw upon the Lifecycle, focussing on governance problems and recommendations for the EHDS.

The analysis on EHDS actors, ethical principles and the four interoperability layers were used to analyse the EHDS proposal, discussing governance options and considerations regarding: (i) the structure of the proposed Health Data Access Body; (ii) the tasks of the Health Data Access Body; (iii) the structure of the proposed EHDS Board; (iv) the tasks of the EHDS Board; (v) and the structure of the proposed cross-border infrastructure.

As the EHDS for secondary health data (HealthData@EU) will depend on data generated through primary care, partly supported by MyHealth@EU, the two systems should not work in siloes. Moreover, this document provides additional governance options ranging from proposals on the structure and tasks of the Health Data Access Body to considerations for the permit application process and the codification of civil society participation. Following the publishing of this report, other JA TEHDAS output will continue to contribute to aspects connected to governance issues, notably by specifying many of the ambiguities regarding the implementing and delegated acts of the EHDS proposal discussed in this deliverable.

Therefore, the document provides concrete input to advance the debate on the governance constellation of the EHDS. While the EHDS proposal provides a vast amount of ambitious options, many governance issues remain to be specified to fully capture the potential of data sharing for secondary purposes and foster citizens' trust to share their health data for the common good.

1. Context - Sharing health data for secondary use

1.1. Introduction

In the 2020 European Strategy for Data, the Commission states the ambition of creating a single market for data in the attempt to reap the benefits of ever-growing volumes of data. Apart from making the data flow effortlessly within and across the EU for the benefit of all, the envisioned European data space should be based on common European values and protected through a trustworthy and fair governance structure, in full respect of privacy, data protection and competition law (1). These data spaces will play a key part in creating an attractive, secure and dynamic data economy.

Health, defined by the Commission as one of the future nine sectoral data spaces, currently suffers from a broad set of issues hindering sharing of health data for primary and secondary purposes. There is fragmentation in governance, access, sharing, and the use of health data at both the national and European level. Diverging and often conflicting national laws limit access to these data in a cross-border setting for patients, researchers, and policymakers (2).

The COVID-19 pandemic has shown that pathogens know no borders, and that cross-border access to health data can help in the response to public health emergencies, for example through the rapid development of COVID-19 vaccines. The access to and the sharing of (health) data for primary or secondary purposes can be regarded as a necessary integral part of Europe's single market, ensuring the free movement of goods, capital, services, and people. Data – and more specifically health data – can arguably be added to these four freedoms (3).

The aim of the project Joint Action "Towards the European Health Data Space" (JA TEHDAS) is the development of sustainable political, legal and technological framework options for the sharing of health data for secondary purposes in the European Union. Being a collaborative effort of 25 EU/EEA and associated countries, the JA TEHDAS project helps both Member States and the European Commission in the development and promotion of concepts related to the secondary use of health data, contributing to the establishment of the European Health Data Space (EHDS).

The JA TEHDAS project facilitates dialogue between stakeholders on sharing health data for secondary purposes in the EU. This also fosters the broader debate on data sharing in the digital age as part of the European Strategy for Data, and the horizontal governance framework for the nine data spaces as formulated in the 2020 Data Governance Act. This document will add to the debate by presenting well-established options for governance models for the EHDS[1].

[1] Also referred to as HealthData@EU and EHDS2 in line with the terminology from the EHDS proposal.

1.2. Background

Within Work Package 5 of the JA TEHDAS project, themed “Sharing data for health”, task 5.4 aims at developing best options for governance of the EHDS regarding the secondary use of health data. This document is the final output of that task.

An earlier product within this task described why the secondary use of health data needs dedicated EU legislation and cannot solely be regulated by horizontal legislation, such as the proposed Data Governance Act (DGA) (4). While being a special category of personal data according to article 9 of the General Data Protection Regulation (GDPR), the secondary use of health data may positively contribute to the well-being of EU citizens. Yet, the sensitive nature of health data necessitates safeguards and requirements for its use, firmly grounded in the right to the protection of personal data as established in article 16 of the Treaty on the Functioning of the European Union (TFEU) and article 8 of the Charter of fundamental rights of the European Union.

Similarly, another product within this task described why the current European organisational structure cannot address pertinent issues regarding the sharing of health data for secondary purposes (5). While propagating the aim of creating a single health data sharing environment , the multitude of institutions already operating on the European level curtails the fulfilment of this aim. Any new governance mechanism should, however, take these institutions into account as it reduces fragmentation in governance, inconsistencies in data approaches, and waste in public funding through overlapping efforts.

1.3. Approach

These two aforementioned products should be read as being the groundwork for the writing of this document. At the same time, this document draws on outputs from other tasks across the different JA TEHDAS Work Packages. Starting in September 2021, work on the document spanned a ten-month period with regular contributor meetings reflecting an iterative writing process. The publication of the EHDS legislative proposal in May 2022 acted as a catalyst for some of the analyses presented in the paper, through the options provided by the impact assessment reports, for example, in the Commission adoption documents (6) (7). Acknowledging the Commission’s ambition to address both the primary use of health data for the provision of care and the secondary use of health data for research and innovation, this document’s main focus is on the governance of the latter.

The first chapter of this document introduced the background of the work at hand. The second chapter sets out how governance is interpreted throughout contemporary EU law. Consequently, in the third chapter, a framework approach to governance is presented, acknowledging the multitude of domains and stakeholders involved. The chapter is structured along the layers of interoperability, and, where applicable, introduces specific data life cycle steps. Chapter four outlines the EHDS proposal and presents additional options and considerations regarding dedicated governance options. The final chapter provides concluding remarks and challenges ahead, likewise mentioning relevant TEHDAS output in the upcoming period.

2. Governance in contemporary EU acts with health data relevance

The following section describes governance elements relevant to the secondary use of health data in the EU in (upcoming) legislative acts. For this purpose, we define governance as "*the act of governing an entity, where the entity is territorially, politically or issue dependently, demarcated by rule-set boundaries*" (5).

Before discussing the DGA, this section will first deal with the Data Act and Artificial Intelligence Act. Some acts are currently under negotiation in various steps of the co-legislative procedure, which means that the original Commission proposal is used as a starting point. Alterations from the Parliament and Council positions are mentioned where relevant. The Digital Market Act (DMA) and the Digital Services Act (DSA) were excluded from the analysis because of their limited relevance to the secondary use of health data. Finally, this section describes how the GDPR has relevance to the secondary use of health data and finishes with a description of ethical values to be taken into consideration in digital health.

2.1. Data Act

In the EU Commission's proposal COM/2022/68 final, more commonly known as the Data Act, two subjects are relevant to the secondary use of health data (8). The first is the combined articles 14 and 15 for data holders to share information (data) to a public sector body or Union institution (or agency or body) in circumstances of exceptional need, such as a public health emergency.

The second is the more general aim of the legislative act to harmonise rules on data generated from the use of products, medical and health devices mentioned in recital 14. Data generated from using these product data should, inter alia, be made more readily accessible to the user according to article 3 and 4 of the proposal. The same chapter introduces additional opportunities for the user to share the generated data with third parties, albeit regulated by rules and obligations for the receiver of this data. At time of writing this report, it is not yet clear to what extent the Data Act will overlap with the scope of the EHDS. This hinges, among other things, on negotiations regarding the Data Act's definition of "data" and "data holder". This definition incorporates the kind of processing that would be considered in scope as well as whether it concerns personal or non-personal health data (and what is considered "health data").

2.2. Artificial Intelligence Act

A proposal and two related legislative activities on Artificial Intelligence (AI) are discussed in the integrated impact assessment IIA of the EHDS against the backdrop of providing a horizontal ethical framework in the future usage of AI (9). This proposal, published in Q1 of 2021, is often referred to as the AI Act. 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 (and health safety) of citizens and the main target of the legislative initiative, high-quality datasets are vital. Such datasets are partly provided by the establishment of the nine

common EU data spaces. The EHDS intends to 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 sufficiently into account.

2.3. Data Governance Act

As part of the first set of measures announced in the 2020 European Strategy for Data (10), the DGA complements Directive 2019/1024 on open data and the re-use of public sector information (Open Data Directive). The DGA proposal was published at the end of November 2020. The final text was adopted in May 2022 (11).

The aim of the act is to facilitate the sharing of data through the creation of horizontal mechanisms that strengthen data availability and foster trust in intermediary services. These aims are realised through rule-specification in three areas: data held by public sectors (chapter II), intermediary services (chapter III), and data altruism (chapter IV). Complementary to the setting of rules, each of the three chapters likewise includes a governance system to augment to proper implementation of the relevant articles. Regarding the chapters on intermediary services and data altruism, chapter V further expands on the particularities of the governance system through an elaboration on the proposed competent authorities in both areas. Lastly, chapter VI envisions the creation of an advisory body through the establishment of an EU-level horizontally operating expert group (governance aspects of the body are excluded in the section as they were already analysed by the JA TEHDAS (5).

The first elements of a body governing (health) data are mentioned in chapter II on data held by public authorities. This chapter creates a mechanism for the re-usage of categories of protected data held by public sectors conditional on the respect of the rights of others, thereby falling under the GDPR provisions and not part of the abovementioned Open Data Directive. The public bodies - relevant actors and types of data specified in articles 3 and 5(1) - are expected to make publicly available the conditions of granting or refusing access for the re-use of data. Such rules should be non-discriminatory, proportionate and objectively justified. At the same time, the body may specify technical obligations to preserve the rights of third parties and charge fees for allowing the re-use of their data. As specified in article 3(3), however, the sharing of data in and of itself is not an obligation for the relevant public bodies.

The provisions of chapter II are realised through the establishment of two distinct governing functions, both providing supportive action to the relevant public institutions. The first is the creation of one or more competent bodies in each Member State. The main task of the envisioned body is neither overseeing the proper implementation of the chapter, like a supervisory body nor making decisions on the granting of access to data, such as a permit authority – although this competence may be granted according to article 12(3). The body instead supports the public authorities by providing secure processing environments for data access, the development of techniques to ensure the privacy of data subjects, and assistance in obtaining consent from data subjects.

Similar support is provided by the second governing function: the single information point (article 8). In line with the institution’s title, this national body is tasked with making available the information on each relevant public body regarding their conditions for re-use and fees

according to articles 5 and 6. The body further receives individual requests for data re-use and forwards these to the relevant competent public bodies.

In chapter III on data sharing services, however, a more stringent system is provided through the creation of a competent authority in each Member State (article 12). This chapter aims to foster trust in data sharing and lower barriers in linking business-to-business (B2B) and consumer-to-business (C2B) services by creating a notification regime for so-called data sharing services. Providers of these services, as conceptualised in article 9(1), will have to notify the competent authority of the Member State in which they operate on several issues. The providers are likewise bound by a set of rules as stipulated in article 11. For example, the institution will have to remain neutral, solely use the acquired metadata to develop their services, implement adequate technical measures to prevent unlawful data transfers, and ensure procedural fairness in data access.

According to article 13 of chapter III and article 23 of chapter V, a new national competent authority is tasked with overseeing the compliance with the articles on data sharing services. In stark contrast to the envisioned tasks of the authority in chapter II, this body will have supervisory capacities through the ability to request information from data sharing service providers under its national jurisdiction. Non-compliance with rules should lead the authority to notify the provider and give it the opportunity to state its views. The authority may likewise require the cessation of misconduct and the proper implementation of the chapter, financial penalties and the request to abandon certain services as the final measure to counteract mishaps.

A less strengthened governance mechanism is provided in the envisioned labelling scheme of chapter IV on data altruism. Data altruism entities, altruism conceptualised in article 1(10) as either the consent by data subjects to process their personal data or the permission of data holders to allow the use of their data without seeking a reward for the general good, will have to comply with a set of general rules. The organisation should be a legal entity constituted to meet objectives of general interest, operate for a non-profit basis, and any activities related to data altruism should take place in a legally independent structure. If an organisation meets these requirements, it may notify the national permit authority of the Member State in which they operate – transparency rules of the notification procedure stated in article 17(4). If deemed sufficient by the national authority, the entity will enter a national and Union register of recognised data altruism organisations and be granted access to the title of ‘data altruism organisation recognised in the Union’.

Next to granting access to the register of recognised institutions, a national authority will likewise be responsible for compliance with the requirements of the chapter. As with the envisioned governance system in chapter III, a competent authority will have the capacity to request information from entities included in the national register of recognised altruist institutions and request the cessation of malpractices. Yet, non-compliance to the request of cessation cannot lead to financial penalties as a final measure, giving the authority fewer capacities compared to its chapter III counterpart. The authority may only remove the organisation from the national register, thereby revoking the organisation's rights to be referred to as a data altruist.

2.4. EHDS actors as defined in the GDPR

This section deals with categories of actors in the future EHDS, as they are defined in the GDPR. It consists of four categories of actors: (i) data subjects, (ii) data controllers, (iii) data processors, and (iv) bodies governed by law. The present legal constellation functions as the basis for the discussion on the EHDS, making no reference to the creation of novel institutions that are not explicitly mentioned in published legislative proposals by the Commission. Terminology used in the GDPR and the DGA proposal are the section's starting point. Explicit references to institutions and articles from the EHDS proposal are not incorporated in the discussion, as these will be part of chapters 3 to 5.

Any EHDS governance system should be based on clearly (and legally) defined roles for the actors that will process personal data, in accordance to the GDPR classification, seen by the EDPS (European Data Protection Supervisor) as vital to a solid and effective governance system (12). The proposed EDPB (European Data Protection Board) guidelines on the processing of personal data for scientific purposes, which aims to give legal clarity to issues surrounding the use of data for secondary purposes, is thus of great importance. The section was written before the publication of these EDPB guidelines.

The description is inevitably a schematic and high-level depiction of a more complicated reality. Various actors are not mentioned as they do not directly process the data but do fulfil a practical task in setting up and maintaining the data space, e.g., by providing services like computing power or storage space. Similarly, where in the four categories an institution falls will depend on the processing operation at hand and its role within said operation: an institution might simultaneously be a data controller for one processing operation and a data processor for another. In other cases, the same institution may be both a data controller for one dataset and a data requester (re-user) for the dataset of another data controller.

Besides, the roles of data processors and controllers and technical procedures for sharing data within the EHDS for institutions dealing with health data are currently not fully fleshed out, a notion reiterated in the proposals on the revamping of the EMA and ECDC (13). In line with the GDPR and the views from the EDPB, terms like 'controller' or 'processor' allocate responsibilities according to the actual role that the institution plays during data-processing activities. In principle, the (legal) classification of an actor as controller or processor should be based on a factual analysis of the case at hand, contrasting a purely a priori designation stemming from, for example, a contract or a legal act (14).

2.4.1. Data subjects

The definition of a data subject stems from the interpretation of personal data, a concept specified under article 4(1) of the GDPR. This article states that personal data "*means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier".*

In our case, data subjects are natural persons whose data concerns health, falling within EU jurisdiction, is specified as personal data related to the physical or mental data of a natural person, and/or reveals information about one's health status (article 4(15)). The collection of such data stems from a broad array of activities and roles that the people fulfil

during their day-to-day activities, such as but not limited to, being a patient. When it comes to using such data for secondary purposes, the role of this actor is contingent on two broad factors: the type of data and the legal basis for processing.

The first factor, type of data, refers to the question whether the data used for further processing is pseudonymised or anonymised. The former process is considered a safeguard to be employed in the context of scientific research as it ensures data minimisation according to GDPR article 89(1), which grants scientific research compatibility with article 5(1)(b) on the further processing of data. While such techniques might minimise data use and make it harder to identify the data subject, pseudonymisation does not rule out re-identification. Pseudonymised data thus falls under the provisions of the GDPR. This is different from the process of anonymisation. GDPR article 2 and recital 26 explain that such data, defined as information not related to an identified or identifiable natural person, does not fall under the GDPR provisions, although the procedural step to render the data anonymous does. Where such data is used for secondary purposes, there is no identifiable data subject to which the data would relate.

The second factor is the legal ground on which the health data was initially collected, justifications for such collection provided in articles 6 and 9 of the GDPR. While article 6 establishes the legal bases on which any type of personal data might be legally processed, article 9 sets out specific conditions under which the general prohibition on the processing of special categories of data, such as health data, are lifted. Both articles provide an active role for the data subject by using (explicit) consent as one of the many legal bases. Article 9(2)(a), on the other hand, gives the Member States the competence to prohibit data processing of certain data types even if the data subject (in theory) consents to the usage thereof.

Moreover, GDPR recital 33, explains that the data subject should have the opportunity to give consent to certain areas of research, as it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of the data collection. The implied idea of more broad forms of consent is discussed in depth by another TEHDAS publication on data altruism (15). The same TEHDAS Work Package also assesses data altruism in light of the DGA and ways in which consent might be used to empower citizens as a co-contributor to the scientific endeavour.

At the same time, other legal grounds may be equally valid reasons to further process health data, such as the provisions on scientific research or reasons of public interest based on Union or Member State law. These grounds are sometimes more appropriate as consent is not a valid reason in cases of a power imbalance between the data subject and controller. Besides, both the EDPB and EPDS have stated on different occasions that these other grounds may be more relevant to the EHDS, as the platform's purpose is to serve the public interest based on the exercise of authority vested in the legal competencies of the data controller. When these legal grounds are relied upon for some datasets, the data subject will inevitably play a more passive role during the Data Lifecycle. In these cases, providing consent is not part of the data subject's interaction with the EHDS, but the data subject's rights remain firmly intact (excluding, for example, the right to erasure). Exercising these rights will be one way for the data subject to interact with the future dataspace.

2.4.2. Data controllers

The second group of institutional actors that will play a vital role in the future EHDS are those actors exercising control over the health data, determining the purpose for data use. While the group of actors belonging to the category is heterogeneous – ranging from university medical centres and hospitals as examples of actors involved in the provision of health care to national health agencies and the private sector- they can be captured using the functional concept of 'data controller', a legal definition derived from article 4(7) of the GDPR: "*'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data".* This definition is likewise closely related to the recently introduced terminology of a data holder in the DGA (12), which is a *"legal person or data subject who* […] *has the right to grant access to or to share certain personal or non-personal data under its control*".

In line with the text of the GDPR, any operation performed on personal data is a form of data processing; the ability to set the boundaries of why processing is taking place and how it will be carried out classifies one as a data controller. Any use of personal data in terms of processing or analysis within the boundaries of the EHDS will be relevant to this categorisation. The level of influence on the (health) data, control over the technical design of a product/related services, and the ability to share or disclose this information is a question based on the reality of the processing activities, not a prior designation, will qualify an actor as either a controller or a processor in the EHDS. That said, it is possible to designate a controller by law.

For example, if several institutions decide to jointly participate in an EU research project, in which each institute uploads personal data to the same secure processing environment, they are considered as joint controllers in any activities related to the project (14). This legal qualification engenders a set of obligations on the part of the controller, a l list of legal duties mostly defined in chapter III and IV of the GDPR. Without going into the specific details of the chapter, the most all-encompassing way to typify these duties is article 25 on data protection by design and by default. Indeed, controllers are the main reference point at which the abovementioned data subjects can exercise their rights (next to lodging a complaint at the relevant supervisory authority), meaning roles and duties should be clearly defined amongst institutions taking part in the EHDS.

Whenever personal data under the legal authority of a data controller is disclosed to another party for further processing or re-use as consumers of the data, the latter party can be typified as a data recipient. Such disclosure should comply with relevant data protection rules, notably a justification for the purpose of further processing in line with the abovementioned compatibility principle of GDPR article 5: *"personal data shall be* […] *collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes".* This compatibility test is, however, not relevant for the disclosing controller whenever there is a legal obligation for processing/disclosure of data.

2.4.3. Data processors

The third group of relevant actors in the EHDS are data processors, who, in line with GDPR article 4(8), are actors deployed by the data controller to process data on their behalf. This broad definition implies that the processor might range from a legal individual to a public or private authority. Essential is carrying out the data-processing related activities as a separate entity in the sense of being an external organisation vis-à-vis the controller, acting on its behalf and under its instructions and bound to the controller either by contract or by law. While the processor might set out a preliminary definition of its data-processing services (how this will take place), it is the controller who makes the final decision on the appropriateness of carrying out said activities.

In that sense, some of the provisions in chapter III of the DGA on data intermediary services are compatible with the tasks of a processor, insofar as carrying out services on behalf of the data holder. Examples of such activities are technical services to enable the sharing or joint exploitation of data between controllers, such as a dedicated infrastructure or platform, and the provision of secure processing environments in which the controller's data can be accessed for re-use. These types of supportive tasks are extensive, thereby vital to the functioning of the future EHDS. Depending on the scope and breadth of the data space, many of the EHDS services proposed by TEHDAS Work Package 7 (16) will be carried out by (or within) some type of data processor.

Any processor of personal data has to comply with a set of rules, as specified in article 28 of the GDPR. The processor is liable in case it fails to comply with these obligations and is likewise accountable to the contractual boundaries as set out by the controller. With regards to research on a dataset containing personal (medical) data, if the endeavour is carried out on behalf of a data controller and said controller sets out clear parameters for the research in a study protocol – i.e. the purpose of processing, the methodology, and study design – the scientist carrying out the actual analysis will be seen as a (mere) processor, even though the data controller might not do anything substantial to the data during the project. If the study protocol is drafted in a collaborative effort with the researchers and the data controller, they are considered joint controllers during the project's timeframe (14).

2.4.4. Bodies governed by public law

The last group of actors are bodies governed by public law with either supervisory competencies over the use and protection of personal (health) data or other tasks relevant to the governance of the health-data landscape. These bodies are established for specific purposes in the general interest, have legal personality, and tend to be funded by the state (16). The competencies related to health data stem from a mandate stipulated in relevant national and EU law, such as the GDPR, the DGA, or any institution described in the envisioned EHDS. While the institutional constellation of the relevant bodies is a multi-level regulatory patchwork and too complicated to be described here – indeed much dependent on the Member State's system of a relatively centralised or decentralised data structure, e.g., having a national permit authority, or the variance in the involvement of ethical committees as a complementary tool to a supervisory authority – some EU structures ought to be mentioned.

The first is the data protection authority mentioned in the GDPR article 4(21) (17), defined as an independent institution in each Member State overseeing the consistent implementation of the GDPR in the respective Member State (chapter VI). These authorities enforce the GDPR, either based on complaints or on their own initiative, with an array of powers, including administrative fines. They also provide opinions on new legislation relevant to the protection of personal data. This system works through a one-stop-shop mechanism: organisations conducting cross-border data processing will primarily deal with the authority based in the Member State of the organisation's main establishment (the lead supervisory authority). EU-level cooperation of these national authorities gets further achieved through deliberation within the EDPB, who can publish opinions on EU legislation and guidelines on data-related issues. The EDPB recently highlighted the importance of including the perspective of data protection authorities in the discussion on the envisioned structure of the EHDS. The EDPB is closely connected to another EU institution: the EDPS. The EDPS is an independent EU body that enforces the data protection rules for the EU institutions, bodies and agencies and provides advisory opinions on proposed Union legislation relevant to the protection of personal data. It also provides the secretariat of the EDPB.

The second relevant structure stems from the DGA and its creation of novel public institutions with supervisory competencies and more supportive tasks (see section 1.3). These new institutions will perform activities somewhat similar to those of market surveillance authorities (excluding the single information point). The single information point is interesting as it closely resembles the construction of national nodes to connect the Member States, who can act as a coordinator between data requests and make databases easier to discover for datasets from public sector bodies. A similar architecture for the EHDS was proposed by the EDPS and has been central to the talks in TEHDAS Work Package 7 on technical interoperability. It would also be somewhat similar to the functioning of the national contact points from the Cross-border Healthcare Directive.

At the same time, a more far-reaching approach is mentioned in article 7(3) of the DGA, which allows Member States to entrust the DGA article 7(1) (supportive) bodies with decision-making powers to grant access to health data held by public authorities. This task would be similar to certain national institutes such as Findata or the French Health Data Hub or the Health Data Access Bodies as mentioned in the EHDS. Any EHDS governance structure will have to work in ways that are complementary to these and other relevant public authorities[2]. This should reduce overcomplication and excessive bureaucratic strain, which is vital to the proper functioning of the future EHDS.

2.5. Building trust in the EHDS

When a legislative act is drafted, it must always have certain underlying principles. Regarding the use of health data, the eHealth Network formally adopted 16 principles on digital health developed during the French Presidency of the Council in June of 2022 (18). With four overarching principles, they aspire to foster shared understanding and inclusive implementation of the EHDS. Inter alia, governance should be founded on principles that closely relate to the more general values (pillars) on which the EU was built. Such principles

[2] see also TEHDAS milestone 5.8 on potential health governance mechanism

should apply to any legislative initiative relevant to the sharing of health data at both the European level and national level:

- **BASE DIGITAL HEALTH ON HUMANISTIC VALUES**

  1. Digital Health complements and optimizes face-to-face healthcare;

  2. Individuals are informed about the benefits and limits of Digital Health;

  3. Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them;

  4. When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias;

- **ENABLE INDIVIDUALS TO MANAGE THEIR DIGITAL HEALTH AND DATA**

  5. Individuals are actively involved in shaping the European and national frameworks of Digital Health and data;

  6. Individuals can easily and reliably retrieve their health data in a commonly used format;

  7. Individuals can easily get information on how their health data have been or may be accessed and for which purpose;

  8. Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable;

- **MAKE DIGITAL HEALTH INCLUSIVE**

  9. Digital Health services are accessible by all, including by people with disabilities or low levels of literacy;

  10. Digital Health services are intuitive and easy to use;

  11. Individuals have access to Digital Health training;

  12. Digital Health services include support through human communication when needed;

- **IMPLEMENT ECO-RESPONSIBLE DIGITAL HEALTH**

  13. Environmental impacts of Digital Health are identified and measured;

  14. Digital Health services are developed in compliance with eco-design best practices;

  15. Re-use and recycling of Digital Health equipment is ensured;

  16. Digital Health stakeholders are committed to reducing their ecological footprint.

2.6. EDPB/EDPS Joint Opinion on the EHDS proposal

On 12 July of 2022, the EDPB and EDPS adopted their joint opinion on the Commission's EHDS proposal (19). While the two bodies expressed positive views on the proposal's aim to strengthen the data subject's control over their personal data, concerns were raised regarding the articles on the secondary use of data (chapter IV). In particular, regarding purposes for secondary use in the EHDS proposal in article 34(1), the EDPB express concern with regards to article 34(1)(f)(g) and points out the need to further delineate these points and their connection with public health and/or social security. These purposes might be further specified to ensure a proper balance between the protection of personal data and public health. Additionally, the proposal's article 38(2) on the obligation of Health Data Access Bodies to only provide 'general public information' would weaken the individual's rights compared to the GDPR.

The EDPS and EDPB also recommend excluding certain categories of electronic health data from secondary use, in particular wellness applications and other digital applications, as well as wellness and behaviour data relevant to health (article 33(1)(f)(n)). Concerning consent-requirements, the data protection authorities pinpoint the lack of clarity as to what these requirements entail at the national level as well as to what step in the procedure may be disregarded by Health Data Access Bodies concerning secondary use of electronic health data, in particular when falling under article 9(4) GDPR.

At the same time, the joint opinion notes that the proposal seems to add another layer to an already complex regulatory and governance field. Regarding the former, interactions with national law concerning cross-border data transfers are unclear, notably when we take the possibility for the Member states to enact additional laws to limit data processing into account (GDPR article 9(4)). Regarding the latter, the proposal might lead to overlapping competencies between the proposed data access bodies, the national supervisory authorities for data protection and the EDPB/EDPS. The tasks for the new public bodies should be clearly defined and cooperation should be ensured through permanent representation of EDPB and EDPS within the new EHDS Board.

3. Governance needs from an interoperability framework perspective

In the following section the elements of the EHDS legislative proposal are being discussed in the context of the European Interoperability Framework together with their needs for (further) governance (20). This framework consists of four layers of interoperability: legal, organisational, semantic and technical, and indicates the necessity of making arrangements between and within different layers to let information flow freely. The discussion on the legal interoperability layer (3.1) is structured around the 7 steps of the EHDS2 Data Lifecycle (figure 1). As much of the suggestions relevant to legislation interoperability will apply to other layers equally - the legislative layer is indeed broad and covers fundamental issues related to governance - the other interoperability layers centres on 'issues' and 'solutions'. This way, the deliverable respects the Data Lifecycle and covers issues not directly related

to said cycle while reducing duplication between the interoperability layers as much as possible.

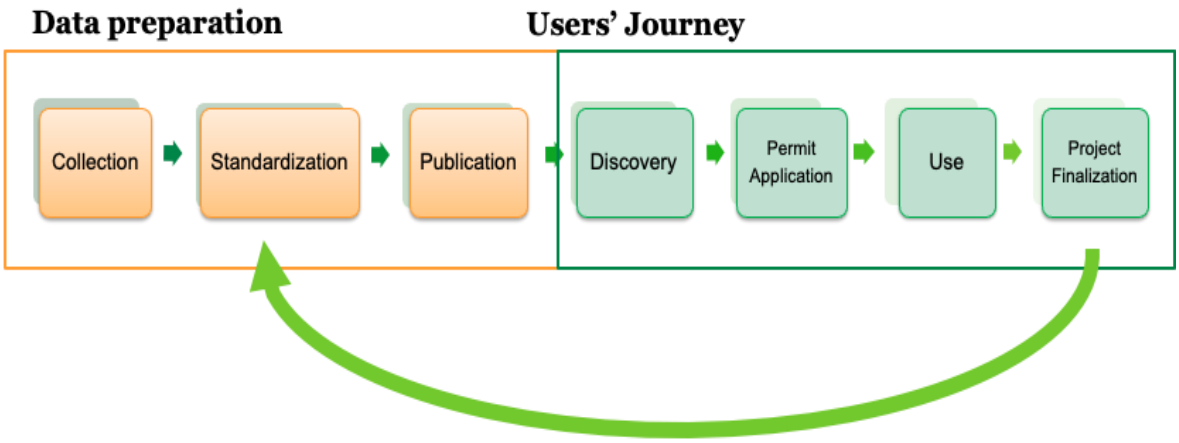

Figure 1: TEHDAS proposal for an EHDS2 Data Lifecycle (21).

The Data Lifecycle is the compendium of steps required to process the health data available in the different holders to put it at the disposition of the final data users (researchers, policy makers, innovation managers, private companies etc.), depicted as the 'Data preparation' phase, as well as the steps the final users should do to actually use the data, depicted as 'Users' Journey' phase. The distinction of Data preparation and Users' Journey has an implication on the main actors within a phase: in the Data preparation, the main actors interacting with the data are the data holders, while in the Users' Journey the main actors are the data users. The data requested is processed according to a set of necessities part of the integration services in the data use phase (22).

The activities that take place at each step within each phase are the following[3]. For the Data preparation they are:

- 'Collection': gathering the data and storing it in a given place at the data holder premises. The gathering may involve moving/copying data from its original location, e.g., a hospital information system, to another location where it will be made available for secondary use;

[3] It is worth to note that this paragraph is largely based on work done in TEHDAS Work Packages 6 and 7. Early documents from Work Package 7 (Milestones 7.1 and 7.2 and Deliverable 7.1) only presented the Users' Journey part of the table above. This is because, from the technical interoperability perspective from Work Package 7, the Users' Journey comprises the phases where the Pan-European architecture operates. In a further stage, the Data Preparation phase was included to provide coherence on the activities performed within each Member State to make that data available to the EHDS in a proper manner in terms of semantic interoperability, thereby providing alignment with Work Packages 6 and 7 proposals.

- 'Standardization': transformation of the data to follow a given encoding of the variables, e.g., ICD-10, ICD-11 or SNOMED CT to codify diseases or clinical procedures, or, more extensively to adapt it to a certain common data model, e.g., OMOP or HL7 FHIR;
- 'Publication': generation of the metadata for cataloguing that describe the actual datasets available to be put at the disposition of the data users, using a given standard, e.g., DCAT-AP, and store of this metadata in a system accessible to the data users to facilitate its further discovery.

In the Users' Journey we identify the following phases:

- 'Discovery': in this phase data users search for the data they need to carry out a specific project of their day-to-day work (answer a research question and/or take decisions regarding new or existing policies or regulations). To perform this search, it is a requirement that the dataset description provided by the different data holders have been properly processed and published in the EHDS through searchable metadata catalogues. Once the search has given the results, the data user should decide on the feasibility of carrying out their study according to the data description found.
- 'Permit application': once the data user has found the required data and the data user has positively evaluated the possibility of performing the analyses he or she requires for their purposes, the data user needs to request the permits for accessing/using the data.
- 'Use': when the data access/use has been granted to the data user, he or she will finally perform the data analyses required as part of their work. The data use phase finishes when the data user has finished its research project or have found the evidence to support new or existing policies or regulations.
- 'Project finalisation': when the research question is answered, the data user needs to ensure a proper disclosure of the findings to the rest of the EHDS users, following the FAIR[4] principles for results data. The findings should also be notified to data controllers to finally inform the data subjects. It might involve providing inputs back to some of the original data holders (to enrich existing data sets), as depicted with the bottom green arrow in the figure.

3.1. Legal interoperability and the Data Lifecycle

"Legal interoperability is about ensuring that organisations operating under different legal frameworks, policies and strategies are able to work together. This might require that legislation does not block the establishment of European public services within and between Member States and that there are clear agreements about how to deal with differences in legislation across borders, including the option of putting in place new legislation" (18).

The GDPR provides a consistent approach for data protection rules throughout the EU. However, despite these harmonised rules, we still see a degree of fragmentation and diverging approaches. Primarily, this is due to the possibilities that the GDPR leaves to Member States to adopt national law in light of, for example, articles 6(1)(e) on legal

[4] Relating to: Findable, Accessible, Interoperable and Re-usable.

obligations and 9(4) on the possibility to introduce further conditions regarding the processing of amongst other things health data. This approach has led to divergence in the implementation of the GDPR in diverse national contexts as evidenced by TEHDAS (2) and discussed in European literature (19) (20). Moreover, Member States have national laws affecting the use of health data (e.g. The Swedish Access to Information and Secrecy Act, while not being a law that is specific regarding health and research, it has provisions that affect health data and its use (21)). Next to differing choices of legal basis driven by national preferences for processing personal data (GDPR articles 6 and 9), semantics and data quality likewise differ at the national level. This legal fragmentation and diverging approaches create practical challenges to cross-border data sharing as further evidenced by TEHDAS (2). The EDPB is aware of this situation and asked the Commission to explore whether in the forthcoming EHDS Regulation, for research projects carried out in multiple Member States and meeting specific criteria, a common legal basis and/or scientific research regime for the processing of personal health data could be provided (22).

Legislative enhancements of the EHDS

To better facilitate data sharing, TEHDAS stakeholders have identified areas for enhancement of the EHDS to resolve or mitigate these data sharing issues in secondary use at the health sector level by legislative means, guidance and best practice (21). This section of the report focuses on TEHDAS recommendations – to be read as potential enhancements to the EHDS - addressing fragmentation and divergence in order to support the development of the EHDS. This focus answers the European Commission and stakeholder calls for further work to support the implementation of the EHDS. For example, 81,7% of the 153 TEHDAS stakeholders surveyed identified 'implementation' as their biggest area of concern following the publication of the legislative proposal (22). The findings are structured to correspond to the TEHDAS Data Lifecycle model and best match the EHDS aim to be user-centric.

3.1.1. Data collection phase

Secondary use / data types

Previous Work Package 5 TEHDAS documents have shown that regardless of a long tradition of cooperation of health data collection between and within countries, semantics and data quality differs at national level (5). In fact, the lack of common European interpretation of 'what is and what is not secondary use of data' was one of 11 priority barriers to cross-border data sharing identified by data users (2). Here, it was indicated that here is no clear legislative definition for 'secondary use'. The term 'secondary use' is not found in the GDPR which only uses the term 'further processing'. Therefore, interpretations have to be extrapolated and differ across Europe. Addressing this issue will be fundamental to the functioning of the EHDS: there can be no proper data collection for secondary use without harmonised interpretations of what secondary processing will entail for the involved parties. Therefore, it is discussed at the beginning of the Data Lifecycle within the collection phase.

TEHDAS work has highlighted that secondary use of data is most commonly understood as data collected for one purpose being used for another (secondary) purpose, such as

research, innovation, policy making, patient safety, personalised medicine, official statistics or regulatory activities. Furthermore, from the Work Packages' 4 and 5 country visits we see that Member States tend to regulate the purposes for which data can be used for secondary purposes. The secondary use of health data is not prohibited under the GDPR as the regulation enables such use whenever certain conditions are met. The terminology used within the GDPR is not 'secondary use' but 'further processing' from articles 5(1)(b) and 6(4).

Against this backdrop, (national) legislators can leave it up to those wanting to use the data to directly apply the provisions from articles 5(1)(b) and 6(4). The controller, in turn, would need to do the compatibility test. Nonetheless, (national) legislators seem to prefer to legislate secondary use and necessary safeguards as a form of further processing. In this case, the legislator conducts the compatibility test and assesses compliance in relation to GDPR article 23 on restrictions. While both applying article 5(1)(b) and 6(4) directly by the controllers and regulation through national law are valid approaches, the Members States seem to solely see secondary use as the product of the legislation on further processing. The EHDS aims to overcome this incoherence stemming from the co-existence of a national approach to secondary use based on law and 'further processing' under the GDPR by defining secondary use within the EHDS proposal article 2. It is paramount that the EHDS's approach to secondary use is also applied at the Member State level to avoid legal uncertainty from competing notions. Yet, the proposal's definition does not take into account what is commonly understood as secondary use within the data protection framework and community (as set out above). Based on the EHDS legislative proposal, TEHDAS stakeholders suggest the following recommendations related to the secondary use of data (7):

- The European Commission and Member States should identify national legislation in place that will impact the access to some of the data categories as proposed in the EHDS legislative proposal during the Council discussions (for example genomic data or data generated by wellness apps/digital health applications that can reveal sensitive information). Alignment with these established national practices (laws) might speed up the implementation of the EHDS;
- Before the adoption of the EHDS legislation, there is a need to introduce a specific legal requirement to regularly review and update the data type, purposes and prohibited purposes listed in articles 33-35 on the request of the European Commission and/or Member States and/or EHDS Board (provided by article 33(7)). This is to ensure that the lists reflect implementation findings and technological advances in health (22);
- TEHDAS recommends the creation of an EHDS Board subgroup to share experiences and promote a harmonised approach to legal basis application within the EHDS, as well as a more harmonised implementation of the GDPR for the re-use of health data (2).

3.1.2. Data standardisation & publication phase

The use of different taxonomy and ontology codes to label the same health condition across Europe and poor data management were two of 11 priority barriers to cross-border data

sharing identified by data users (2) and Work Packages 6 and 7. Work Package 6 analysed 31 initiatives operating in specific health care domains with the majority focusing on cancer, infectious diseases (incl. COVID-19), rare diseases, genomics and population health. Only five out of thirty-one initiatives have a Data Quality Framework implemented and operational and four of those had the framework documented and publicly available. Metadata catalogues were available at a third of the initiatives (23). The EHDS proposal likewise deals with these issues in article 44 and 56 (see page 35 of the current document for a reflection on data quality principles within the proposal).

In article 55, the EHDS legislative proposal has taken into account specific TEHDAS recommendations on metadata catalogues and use of standardised terminologies by placing a legal obligation on Health Data Access Bodies to inform data users about the available datasets and their characteristics through a metadata catalogue (21) (6). Furthermore, the proposal commits to set out the minimum information elements data holders are to provide for datasets and their characteristics. The TEHDAS stakeholders welcome the European Commission's attempt to improve discoverability and compatibility of datasets across Europe. This could be achieved either via implementing and delegated acts or non-legislative measures such as European norms, guidance and best practice via the proposed EHDS Board. TEHDAS stakeholders would further encourage the European Commission to consider:

- A predetermined list of several common interoperability standards including terminologies, ontologies and classification systems. TEHDAS Work Package 6 Milestone 6.2 has identified relevant standards and data models for semantic harmonisation and the forthcoming Deliverable 6.2 will propose a semantic interoperability framework for the EHDS. The objective would be to align interoperability standards while still allowing a necessary level of national flexibility. To ensure common understanding the interpretation would need to be specified for each standard and not just the model or element. Comprehensive mapping between standards would support implementation at operational level and EHDS could build on existing projects mapping classification standards, e.g., the Observational Health Data Sciences and Informatics (OHDSI) (2) (24));
- A standardised data dictionary with definitions and terminologies which data controllers should abide by (2). This dictionary should provide clear guidance on language norms as well as how they will be governed, with an eye to convening interpretations at global level especially for pandemic preparedness and for any changes in the delivery of care e.g., owing to climate change.

3.1.3. Data discovery phase

Guidance on how to support data discovery should outline the parameters for the possible services as developed by TEHDAS (21) including:

- Data search: an interface for data users to describe the existing data they need and find it in the national node registries. In general, the data described is expected to be a cohort of patients with a specific inclusion criterion, such as a given diagnosis or certain

type of intervention (codified using a standard encoding system) or other characteristics of interest (age, sex, etc.);
- Data search broadcast: a service to send the searches among the national nodes. Preferably, the broadcast should be done in a manner that is transparent to the data user doing the search.

In both cases, the results of the data search should provide an informative summary regarding the number of records found, high-level quality measures and other information useful to the data user to decide the potential feasibility of the further actions. In the data sharing initiatives analysed by Work Package 7, half of the sites provided a search portal with the capacity to launch queries with some level of complexity, including concept browsers, topic or keyword search, actual data scanners or info about publications based on archived data (21).

3.1.4. Data permit application phase

TEHDAS Work Package 7 identifies a need to establish national designated bodies granting or rejecting the access to health data for secondary use (24). The current legislative EHDS proposal states that Member States will have one or more Health Data Access Bodies handling and enforcing the provisions applying to the sharing of electronic health data between data holders and data users. Overall, there is a risk that this approach - i.e., multiple Health Data Access Bodies at national level - may not mitigate the fragmentation across Member States which has been creating challenges so far[5].

Permit application services

Previous TEHDAS work has highlighted the challenges and delays data users face due to requirements to submit multiple data access requests often in different formats (2). Following the legislative proposal further consideration should be given to the need for researchers to maintain a direct link with the data holder in certain circumstances to make sure that the researcher receives the right data with the right quality. It is not feasible for this function to be completed by the national node due to the level of detail of the dataset required. To support data discovery TEHDAS stakeholders have identified the need for consideration of the following points outlining the parameters for the data permit applications, contracts, and training (21):

- Permit application form: an interface or form detailing the specificities of the data request, including the data specification, the end-use or purpose, data user information, and study protocol;
- Permit acceptance and management: the services to forward the permit application among the national nodes as needed and to coordinate the different boards or bodies in charge of accepting the application. This may include data hubs representatives as well as ethics committees' approval to align approaches regarding ethical issues raised

[5] See also chapter 4 for further discussion on the Health Data Access Bodies.

by secondary use (such as is the necessity of the data request, the potential soundness of results, and potential right infringements on the individual);
- Contract signing: after the acceptance of the permit, a service to facilitate the signing of contractual commitments between the appropriate signature parties. Optionally, it may include the registration of the study;
- Training: a service/services of online courses for a proper use of the EHDS services and data. Training may be required as a precondition for the data access permit as it fosters digital health literacy.

Mutual recognition of data permits and ethical reviews

The EHDS legislative proposal sets out a mutual recognition principle, under which a data permit issued by one concerned Health Data Access Body may benefit from mutual recognition by the other concerned Health Data Access Bodies (6). TEHDAS facilitated workshops have shown that general European stakeholders support the intention behind the mutual recognition principle i.e., to reduce multiple data access requests, however they have concerns about how the mutual recognition principle will affect national health competence. If the mutual recognition principle for data permits is to be adopted, TEHDAS stakeholders recommend that the European Commission draws extensively on existing examples such as the EMA MRA-model (25) and the cross-border healthcare directive, as well as maintaining a close synergy with the work tested in the HealthData@EU pilot (5).

At the same time, the ethical review prior to granting a data permit is a source of fragmentation, even within Member States. Mutual recognition where one research ethics review committee accepts the processes implemented to come to decisions of other ethical review committees would be a step forward towards mutual recognition of ethical reviews. This would likewise imply a need to start a discussion on minimum ethical requirements, as national discretion should be respected. EU-funded research projects might lead the way in the interpretations of ethics when several countries are involved.

Third country access

The COVID-19 pandemic has highlighted the value of global health and collaborations and therefore Chapter IV of the EHDS legislative proposal setting out a secure route for third country access is welcome. In terms of next steps, specific recommendations for the implementing and delegated acts, based on TEHDAS findings and co-developed with our stakeholders, include:

- To clarify how article 27 on CE markings should apply to third countries. For example, to confirm whether there will be mutual recognition arrangements for conformity assessment in other countries;
- It should be possible for third country non-governmental organisations (e.g., national research institutes) to become the national node, in lieu of governmental participation in Healthdata@EU;
- To create a role for a representative that acts on behalf of the international community (e.g., WHO or Global Digital Health Partnership representative) in the overall governance of the EHDS to support with coordination in light of wider global health

issues. Ensuring the global context is considered within the EHDS governance will also support European life-science industries and enable clinical trials to run more effectively. Without this global link, there is a risk of divergence with other global actors, such as the United States, who have a significant influence on the Electronic Health Record market. Work on third country access, conducted by relevant TEHDAS members and partners, will continue in 2023.

Joint controllers

It is stated in article 51 of the EHDS legislative proposal that both the Health Data Access Bodies and data users as well as Union Institutions shall be joint controllers when processing health data for a data permit (6). In article 52, it is further mentioned that in the case of two or more Health Data Access Bodies using a secure processing environment provided by the European Commission, the Health Data Access Bodies shall be joint controllers whereas the European Commission shall be the processor. It is also stated that the European Commission shall only process health data on behalf of the joint controllers. This constellation might make it unclear when the European Commission (Union Institutions) will act as a joint controller, and when they will act as a processor, or if they will potentially act as both (6). Difficulties regarding this division of GDPR roles might be explored during the Council discussions.

3.1.5. Data use phase

Data processing

TEHDAS further recommends that the data should be processed and analysed in a special "safety room", from which only aggregated data and outputs can be shared with the public (2). The EHDS legislative proposal adopts this recommendation in article 50 stating that the processing (as well as uploading of, access to and downloading of electronic health data) should be done through a secure processing environment following a list of security measures, for which the European Commission shall provide *"the technical, information security and interoperability requirements"* (6). Further guidelines on technical description, information security and interoperability elements of these secure processing environments will further developed in Work Package 7 as part the final Deliverable 7.2. Recommendations on the respective legislative article can be found in chapter 4.

Anonymisation and pseudonymisation

Furthermore, article 44 of the EHDS legislative proposal states that electronic health data shall be provided in an anonymised format as much as possible, with pseudonymised data provided only where the purpose of the data user's processing cannot be achieved with anonymised data (6). While the legislative proposal clearly sets out the data format, the challenges experienced by differing interpretations and lack of common definitions of sufficient anonymisation and pseudonymisation, as well as the purpose for using both data processing methods are not addressed. TEHDAS stakeholders are divided on how best to resolve these interpretations at European level. The following options might be considered:

- One option would be for the European Commission to create legal text that clearly defines ‘render anonymous’ and ‘undergone pseudonymisation’ (GDPR terminology) specifically for the EHDS (2). This high-intensity intervention would resolve the lack of alignment, creating harmonisation within the EHDS, but would not allow for the same level of flexibility at national level as currently is in place;
- A lower intensity and non-legislative option would be to create a common reference document for the EHDS translated into all EU languages that captures Member States’ anonymisation and pseudonymisation processes, national level rules and interpretations (2). This option would mitigate the lack of alignment and provide more national flexibility but would need to be maintained by the European Commission and regularly updated by the Member States. Fortunately, guidelines on pseudonymisation and anonymisation are on the EDPB work programme (26).

It is also worth noting that approaches taken so far, consisting of low intensity instruments such as guidelines and recommendations aimed to support interoperability, have not produced the desired result for European harmonisation (27) (28). We need steering from European decision-makers on what constitutes sufficient anonymisation and pseudonymisation. Guidance on these issues is expected to be provided by the final Deliverable of TEHDAS Work Package 6.

Patient safety or health and re-identification

Without having a secure re-identification method, it becomes impossible to communicate relevant health findings and hence, this could potentially put patients at risk. TEHDAS stakeholders acknowledge that the EHDS legislative proposal sets out a re-identification principle on health, under which a Health Data Access Body, when informed by a data user of a finding that may impact the health of a natural person, may inform the natural person and treating health professional about that finding. TEHDAS stakeholders support this principle while recommending that the European Commission includes, within the annual reporting duties established or the Health Data Access Bodies, the inclusion of the number of communications received from data users in this regard.

At the same time, to foster trust in the EHDS, health data received under the secondary use regime should be considered 'privileged information'. The disclosure and misuse of such 'privileged information' should be sanctioned severely.

3.1.6 Project finalisation phase

The project finalisation phase is the last phase in the Data Lifecycle. It starts when the research question is answered, or the evidence required to support a legislative proposal or regulation has been found. The EHDS legislation sets out reporting requirements for both data users and Health Data Access Bodies to make public the results or outcomes of the projects for which the electronic health data were used (articles 37-39, 46), reflecting TEHDAS advice (24).

To further ensure a proper disclosure of findings, the EHDS should include clear guidelines for results cataloguing. Data and metadata, and any other supplemental material (analysis

scripts, manuals, others), should be included to guarantee the reproducibility of the analyses by other data users, following the FAIR principles. Results cataloguing is expected to facilitate the further re-use in connection to the data search services of the data discovery phase of the Users' Journey (24).

3.2. Organisational interoperability

"Organisational interoperability means documenting and integrating or aligning business processes and relevant information exchanged. Organisational interoperability aims to meet the requirements of the user community by making services available, easily identifiable, accessible and user-focused" (29).

3.2.1. Organisational issues

According to the allocation of competencies as identified in TFEU article 168 (30), Member States have the responsibility for the organisation of their health policy and the delivery of health services and medical care. The case studies from earlier TEHDAS work indicate that Member States and associated countries have national health data management models ranging from centralised models to decentralised and federated systems (2). The case studies likewise stressed that these diverging starting points would need to be taken into consideration in the development and implementation of digital health legislation as well as the underlying infrastructure for the EHDS.

While Member States have diverging health systems, it is difficult to assess in which Member State what kind of system is in place without doing research or having high level-knowledge of the regulatory patchwork (dependent on agency as opposed to institution). Such knowledge gaps are also very much relevant to the relationship with other similar EU projects, often working on an ad-hoc/siloed basis with links based on the participation of individuals in multiple projects or awareness-raising via a continuous stream of information-sharing in newsletters, webinars or conferences.

At the same time, there is a clear knowledge gap regarding the type of data and the access to such data both with and beyond one's Member State of residence. Research projects have to continuously undergo the same burdensome procedures to access relevant datasets, a process not streamlined across data controllers (31). This concern stems from the views of both private authorities and scholars when they wish to make use of the health data for the development of innovative, data-driven health solutions (2). Within the Data Lifecycle, this would be most relevant to the data discovery and application phases.

Previous TEHDAS work has evidenced that several Member States experience challenges related to policy barriers to public authorities undertaking data linkages when developing health data infrastructure. As a result, TEHDAS has developed a catalogue of EHDS services for secondary use of health data report. Furthermore, an initial architectural concept has been proposed by TEHDAS, which roughly consists of a system of nodes connecting data holders and users using secure processing environments as well as other nodes to provide cross-border services (21).

The EHDS legislative proposal captures the TEHDAS catalogue and architecture concept into specific and detailed legal provisions (6). Article 53 of the legislative proposal states

that the European Commission will, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests. While the common rules for data delivery still need to be defined, to ensure the smooth implementation of the EHDS the European Commission should draw on learnings from established and mature data access authorities as outlined in TEHDAS work (5). These bodies have experience with developing and implementing legal frameworks for secure and privacy-conscious data use and can initiate the frameworks required for the forthcoming implementing and delegated acts.

3.2.2. Organisational solutions

Standard development

To counteract the fragmentation identified above, the EHDS could develop or propose a suite of standards that would make the interaction between actors less cumbersome during the data discovery and permit application phase of the Data Lifecycle. Standard development on the following issues might be of relevance:

- Application forms to data access for secondary use, thereby making the process more efficient and transparent;
- Similar access conditions across the EU, reducing biases and ensuring a similar treatment in different Member States;
- Standard covenants for cooperation/data access agreements between organisations, promoted by the TEHDAS joint action to accelerate data sharing.

Standards on these issues could come to fruition within the EHDS proposals' implementing acts on standard development (e.g., article 53(3)). A less stringent option would be the enactment of an article 40 GDPR or EHDS code of conduct and relying on EDPB guidelines[6]. Alternatively, a harmonised procurement contract template could speed up the establishment of research collaborations between institutions.

Standards might likewise be developed for consent forms whenever used as the legal basis for data sharing. While the EHDS proposal currently does not rely on consent as the legal basis for data sharing for secondary use, standardisation on this issue might be a fruitful alternative in the future, depending on the functioning of the current system. Such use of consent might provide a synergy between the second aim of EHDS recital 1 on improving the secondary use of health data and the first aim of this recital on access and control by natural persons over their electronic health data in the context of health care (primary use). At the same time, attention should be paid to the ways in which citizens can exercise their rights conform the GDPR. The following elements are important to consider for these types of standards:

- Standard set of information about the data users that will use/re-use the data. While difficult to assess a priori in certain research cases, being as transparent as possible is seen as a necessity by the EDPB (32);

[6] See also 3.1.5. for a discussion on voluntary mechanisms

- Information on the rights of the data subject as defined in the GDPR and in light of EHDS article 38(2) on provided general information to the data subjects;
- Information on the legal basis for data processing conform GDPR articles 6 and 9;
- Information on re-use/asking explicit consent that the data subject might be approached for specific research projects in the future. This might further include an option for the data subject to agree to the use of personal data for specific research areas as opposed to individual projects (see GDPR recital 33). Whenever approached for a project, the goal of the endeavour and the organisations participating should be stated clearly (see the standardised European Reference Networks consent form (33).

Using these types of documents to promote secondary use, however, implies the broad adoption of standardised consent forms at the source of the data collection[7], which is often the primary care process for health data. While the TEHDAS project only deals with the secondary use of data, adding an article on standardisation at the source, where the entity responsible for setting up and managing the EHR system technically implements the consent-requirements, would be a fruitful addition to the EHDS and a strong link between the articles on EHDS1 (for primary use) and EHDS2 (for secondary use).

Infrastructure development

The standards above could be supported by the creation of national contact points, where public information on national data sources can be found to support the data discovery phase. Within the EHDS proposal the structure is formulated in article 52 on the cross-border infrastructure. Similar to the services provided by the ELIXIR project, the EHDS might have a central hub/office funded at the EU level, while the distributed nodes could be funded nationally (34). This structure could be linked to the DGA information point and will need to be codified in national law, similar to most of the institutions described in other TEHDAS documents (31). The national contact point should at least contain the following information per dataset:

- General information on content of the data (e.g., year of collection, target population, type of data etc.);
- General information on the data controller;
- What needs to be done in order to re-use the data (technical needs, need to ask for consent if necessary, conform national law). Much of the work on EHDS services from Work Package 7 deal with same issues in more detail (21).

Such a structure would be akin to a federated system (35). EU law would provide a legal basis to harmonise data processing for research (and potentially other secondary use), leading to an EHDS that is technically, semantically and legally interoperable. Individual access to such a space could be ensured using the eIDAS notified scheme (likewise relevant in light of the revamping of the eIDAS regulation) (36).

Another option would be a more centralised system akin to the proposed structure within the DARWIN project. Here, a central third-party coordination centre (situated within The Netherlands) operates all technical and methodological services for the provision of access to data and executes scientific studies. As stipulated by the JA TEHDAS, the aim of

[7] See also paragraph 2.4.1

DARWIN is to build a network with the coordination centre as the central hub for data, expertise and services with distributed data access amongst the involved parties (5). After formulating research questions, scripts will move from the coordination centre towards the data holder. The data holder, in turn, only shares the aggregated results with the coordination centre, which would fall outside of the GDPR rules on personal data. For the running of the scripts, however, the data holder will process personal data and require an appropriate basis to do so.

At the same time, researchers are invited to deposit data in controlled access repositories. These repositories would manage controlled access mechanisms and have established data sharing contracts. Access for academia should be possible for justified research projects without additional charges (2).

3.3. Semantic interoperability

As per the European Interoperability Framework, semantic interoperability ensures that the precise format and meaning of exchanged data and information on the data is preserved and understood across data sources and in the exchange between parties (20).

3.3.1. Standard implementation

Interoperability standards at the semantic and syntactic level are key to assure comparability across data holders, across Health Data Access Bodies and the proposed cross-border infrastructure's authorised participants in HealthData@EU and, thus, to facilitate the reuse of data. While TEHDAS has identified a broad list of relevant standards for harmonised semantic and syntactic interoperability, the widespread (harmonised) adoption of these standards is often lacking (37). Using different standards to label the same health conditions hampers the reuse of health data, identified by data users as a barrier to data sharing for secondary purposes. At the same time, many initiatives operating in the health domain do not have a data quality framework. Against this backdrop, the TEHDAS Joint Action provides recommendations on:

- Standards on data discoverability (i.e., to facilitate access as a previous step for meaningful processing of the datasets available for HealthData@EU);
- Standards that allow semantic interoperability (i.e., for the development of common data models);
- Standards that facilitate the communication across nodes of the proposed HealthData@EU infrastructure at the syntactic level.

Although interoperability standards are relevant for the entire data-life cycle, the principal aim of TEHDAS is not to provide guidance to data controllers at the origin of the data source (e.g., data from provision of care or public health, patients or citizens) on what standards they should use to collect data for primary purposes. Instead, the aim is to provide guidance to the European Commission's proposed EHDS HealthData@EU infrastructure (EHDS article 52) regarding Health Data Access Bodies and authorised nodes on the standards that could be used for the three aforementioned purposes. The eHealth Network is doing this work via the working group on standards.

More specifically, along the Data Lifecycle, there are four steps where the proposed Health Data Access Bodies and nodes should pay attention to interoperability standards:

- In the harmonisation of the data collections (i.e., the effective application of semantic interoperability standards);
- In the publication of the data sources and data collections (i.e., interoperable cataloguing of the data sources and collections, their provenance, the access procedures, and some features on the content of data source, for example, relevance, coverage, completeness or timeliness);
- When access is granted to the data users and data sources have to be integrated (i.e., transformed according to the research protocol and linked in an interoperable manner) and sensitive data anonymised or pseudonymised;
- When the research query comes to an end, there is a need to archive research output (i.e., the effective application of the FAIR principles using publication standards, such as the one's developed by DCAT-AP or Open Science). These might become an enrichment of the HealthData@EU knowledge base.

3.3.2. Implications for governance

If the proposed HealthData@EU structure of national Health Data Access Bodies gets ratified, two governance elements are to be considered during the implementation of the EHDS. The first is compliance with the proposed legal provisions for Health Data Access Bodies to (regularly) audit data quality (e.g., proper use of harmonisation and publication standards by public sector bodies holding data); transparent data processing (including linkage and de-personalisation and re-identification procedures); and clear standardised information for the data access procedures (such as a template protocol and data management plan). The second is how standards at each of the four steps mentioned above are effectively implemented, maintained and supervised.

The technical interoperability layer as part of the abovementioned data quality framework foresees a threefold approach to the effective implementation of the data quality principles in the proposed HealthData@EU structure. Some data quality measures will have to be translated into legislation as a minimum to ensure a harmonised approach to data quality (e.g., the requirement of regular auditing against a well-developed data quality framework). Other measures could be solely kept as recommendations within the EHDS (e.g., recommendations on archival and open access publication procedures when the use of data finalises).

A third approach would entail continuous data quality improvement principles of assessment, comparison, and promotion. The data holders could be graded against benchmarks and receive quality labels accordingly. This system could be implemented throughout a self-assessment methodology: data holders will be allowed to apply for labelling after self-assessment, and Health Data Access Bodies would authorise the promotion of such labels. The European Commission would be charged with providing the label and the ex-post control of the overall compliance.

3.4. Technical interoperability

"[Technical interoprability] *covers the applications and infrastructures linking systems and services. Aspects of technical interoperability include interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols* (38)*."*

3.4.1. The federated peer-to-peer network

During the initial discussion of the JA TEHDAS proposal and in further conversations during the stakeholder forums, the proposed architecture to support the technical elements of the EHDS is a so-called 'federated peer-to-peer (P2P) network' (36). As described by the TEHDAS, a P2P network is an architecture of a computer network where the information (i.e., health data) is distributed among the member nodes (24). This system is in stark contrast to a client-server scenario, where all information is stored at a single node. A federated P2P was decided upon as each node can operate isolated, providing a certain number of services to their users' community, e.g., access and analyse the data available within the nodes. This architecture has nearly exact representation in the proposed HealthData@EU infrastructure defined in the article 52 of the EHDS.

Yet, within the initial conception of the P2P network, the capabilities of the P2P infrastructure's nodes were not defined. For example, there might be nodes that represent the Member States, research infrastructures (BBMRI, ELIXIR) or EU regulatory agencies (EMA, ECDC). In addition, there might be other nodes managed at the EU level to help with some of the necessary services (named *central services nodes)* (16).

3.4.2. Technical issues

Much of the discussions on the P2P network happened against the backdrop of a set of problems identified by the TEHDAS joint actions relevant to the technical dimension of the interoperability framework. In TEHDAS deliverable 5.1 as well as the preparatory analyses carried out during the initial phases of the TEHDAS Work Package 7 activities, four main limitations were identified (2). These should be tackled within the EHDS to augment the secondary use of health data across the European borders:

- Limitations to discovering data: the data available in the different data controllers is not properly classified or publicised, avoiding its discoverability by data users[8];
- Management of data permits for secondary use: the process to grant access to the data is not homogeneous among existing data sharing initiatives across the EU;
- Limitations on the data mobilisation for data analyses: a clear position of the Member States is needed on cross-border health data disclosure. *A priori*, data mobilisation should be minimised;
- Limitations on results sharing: it is not defined how to verify or audit that the results from analysis using data from the EHDS can be easily disseminated.

3.4.3. Technical solutions

To overcome these four challenges and give additional input to the implementing and delegated acts of the EHDS proposal, earlier TEHDAS work proposed a model for the structured process a data user should follow to discover, obtain permits, perform the analyses and, finally, share research results (21). The rest of Work Package 7 has been

[8] See also 3.2.1 of the current document

structured according to present the specificities of the services required to support such Users' Journey, i.e., the basis for the technical interoperability. The necessary steps to smoothen data sharing during the whole User's Journey have been provided by TEHDAS Deliverable 7.1 on the minimum set of services in the EHDS2[9].

In addition to technical interoperability challenges, it is important to mention an element introduced in earlier TEHDAS work relating to the location of the technical services defined in the EHDS proposal. These services may reside in the HealthData@EU nodes, in the central services node or in a hybrid approach, combining both locations (24). It is the aim of the final Deliverable of the TEHDAS Work Package 7 to define the options for architecture, i.e., how to locate and distribute the services, as well as the infrastructure options, i.e., the hardware solutions that will support the operations. These architectural and infrastructure options will be then related to the governance options for the infrastructure, for example, a purely P2P approach, where all the services are located in the nodes, may only require a governance body with representatives of the Member States, while a hybrid approach may require a government body with the participation of the Member States plus representatives of a European-wide body, representing the central services requirements.

Moreover, there will a specific set of guidelines accompanying the final Deliverable 7.2, elaborating at finer level of detail recommendations to provide solutions to the first three limitations listed in the previous subsection. These guidelines will also give clarity to relevant EHDS articles:

- Guidelines for secure processing environments on technical, security and interoperability requirements (EHDS article 50(4));
- Guidelines for management systems to record and process data access applications, data requests and the data permits issued (EHDS article 37(1));
- Guidelines for national dataset catalogues publicly available to register and facilitate the discovery of health datasets available for secondary use (EHDS article 37(1)).

4. Enhancing the EHDS through addressing governance needs

Having elaborated on the four interoperability layers and the necessity to include these layers into the EHDS governance structure, the current section deals with the EHDS proposal and potential enhancements to the legal text proposed by the Commission in May of 2022 (6). While the interoperability layers are often not mentioned by name directly, they were vital to the drafting of the suggestions.

The chapter follows the structure of tables, with each relevant subject for secondary use having one table. These subjects were agreed upon by the contributors of the Deliverable: Health Data Access Body, EHDS Board and the Cross-border infrastructure (HealthData@EU). The subjects are divided into discussions on structure and tasks (except

[9] These steps were likewise clarified in the discussion in the current deliverable's section 3.1, providing many options to augment the effective functioning of the future EHDS.

for the Cross-border infrastructure), resulting in five tables. Each table includes the current legislative formulation (left-hand side of the table) and additional governance proposals (right-hand side). The right-hand side consists of additions to the proposal (option) and things that might be taken into account by the co-legislators (consider).

Before delving into the specifics of the proposal, however, it is important to assess the grounds on which acting on European scale was deemed necessary. As stated in article 5(3) of the Treaty on European Union (TEU), the Union shall only do so if the objectives of the proposed action cannot be sufficiently achieved by the Member States (subsidiarity) (39). A proposal related to public health policies, such as the EHDS, requires a thorough reasoning to justify the legislative intervention as the competencies of the Union have been circumscribed under article 168 of the TFEU (40). Against this backdrop, the proposal is based on a dual legal basis from the TFEU, article 16 on the right of personal data and article 114 on the competence to enact measures to harmonise the workings of the internal market. The proposal further indicates that the legislative measures do not go "beyond what is necessary to achieve the objectives" (proportionality). Recently, however, some reports have criticised the use of these two articles as insufficiently answering the subsidiarity question for the EHDS (41) (42).

Table 1. Health Data Access Body - Structure

Formulation in current EHDS proposal	Additional governance considerations
• *Member States shall designate one or more health data access bodies responsible for granting access to electronic health data for secondary use* (art. 36(1)). • *Member States may either establish one or more new public sector bodies or rely on existing public sector bodies* (article 36(1)). • *Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating requests with the other health data access bodies* (art.36(1)). • *Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers* (art. 36(2)).	• **Consider:** developing EDPB guidelines or GDPR article 40 Code of Conducts to establish necessary standards for technical and semantic specifications. • **Consider:** reducing fragmentation by curtailing the discretionary leeway to split up tasks of the data access body on the national level. The latter option might take into account combining the function of the Health Data Access Body with the national contact point.

Table 2. Health Data Access Body – Tasks	
Formulation in current EHDS proposal	Additional governance considerations
General tasks of the Health Data Access Body • [Health data access bodies shall] *decide on data access applications* […] *to access electronic health data falling within their national remit for secondary use* (art. 37(1)(a)). • *Process electronic health data for the purposes set out in Article 34* […] *and put those data at the disposal of data users in a secure processing environment* (art. 37(1)(d)). • *Process electronic health data from other relevant data holders based on a data permit or a data request for purposes laid down in Article 34* (art. 37(1)(e)). • *Cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment* (art. 37(1)(m)). • *Facilitate cross-border access to electronic health data for secondary use hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission* (art. 37(1)(o)).	**General tasks of the Health Data Access Body** • **Consider:** the proposed Health Data Access Body will have to carry out a multitude of tasks, ranging from data their access application assessments but also retrospectively reviewing those performed by single data holders, to the supervision of compliance. Investment in technology and human resources will be a necessity if the Access Body wants to handle data requests in a timely manner, thereby reducing the potential for a bottleneck in the cornerstone of the EHDS (increase efficiency of data requests). At the same time, the sensitive nature of health data implies that corners should not be cut when it comes to the monitoring of compliance with the rules for data users and the security of the processing environment. • **Consider:** the proposal might specify whether and how the Health Data Access Bodies shall monitor the public values generated from the secondary use of health data. In general, it will be challenging for the Health Data Access Bodies and Member States to balance processing data access applications and monitoring and auditing. • **Option:** the Commission and Member States will have to find a way to share the financial burden for the initial implementation of the envisioned Access Bodies. One option might be setting up a system akin to the Elixir project, where a central hub is funded at the EU level (the Elixir Board), and the national nodes are funded nationally. The former institute might purely support implementation by sharing information and best practices on national implementation without having a mandate on the actual granting of permits.

Data quality • [Health data access bodies shall] *cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label* (art. 37(1)(j)). • *The competent bodies shall inform the data users about the available datasets and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, nature of electronic health data and conditions for making electronic health data available* (art. 55(1)). • *The Commission* [...] *shall set out the minimum information elements data holders are to provide for datasets and their characteristics* (art. 55(2)). • *Datasets made available through health data access bodies may have a Union data quality and utility label provided by the data holder* (art. 56(1)). • *Datasets with electronic health data collected and processed by private, public or not-for-profit bodies or individuals with the support of EU or national public funding shall have a data quality and utility label* (art. 56(2)). • *The Commission shall* [...] *set out the visual characteristics and technical specifications of the data quality and utility label* (art. 56(5)).	**Data quality** • **Consider:** while the EHDS proposal sets out the necessity of data quality labels for datasets supported by EU or national funding, the way in which these labels will be granted is currently left unspecified (apart from the mentioning that the Health Data Access Bodies will assess whether a granted label is valid). TEHDAS Work Package 6 will deliver in April 2023 guidelines on data quality and utility label with the requirements for the implementation of a maturity model for data holders and datasets on data quality. • **Option:** an additional article might be created that specifies the procedure of the data quality assessment. For instance, data holders will be allowed to apply for labelling their data collections after self-assessment with the Health Data Access Bodies promoting such labelling. The European Commission would be in charge of providing the label and the ex-post control of the overall compliance. • **Option:** All data holders and datasets available in the EHDS generated with public funding should have a data quality and utility label. All other datasets should have at least a dataset descriptor. Notably, in relation to the use of EHDS datasets within the proposed AI regulation, the highest standard should be ensured to avoid bias from any dataset used within the EHDS. Here, an external independent assessment might be mentioned as voluntary within the EHDS proposal. • **Option:** the proposal might set out the option for Member States to introduce more stringent data quality rules for datasets under their jurisdiction whenever a self-assessment procedure is decided upon by the European Commission.
Secure processing environments • *The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements* (art 50(1)).	**Secure processing environments** • **Consider:** as all processing of personal data within the EHDS will be carried out within a secure processing environment, all Member States should ensure sufficient expertise within the Health Data Access Bodies. Currently, such

• *The health data access bodies shall ensure that electronic health data can be uploaded by data holders and can be accessed by the data user in a secure processing environment. The data users shall only be able to download non-personal electronic health data from the secure processing environment* (art 50(2)). • *Where requested by two or more health data access bodies, the Commission may provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50* (art. 52(10)).	expertise is diffuse and may not be easy to tap upon for some countries. Yet, no compromises can be made due to the sensitive nature of personal data and the expectation that the citizen's data will be processed using the most secure techniques (citizen trust). • **Consider:** Member States might want to draw upon the expertise of other (national institutions) who have already worked with secure processing environments. Such an option is currently not provided by the proposal. These organisations might be formally codified as a public institution, such as the national statistical office. • **Consider:** Finland currently uses nine secure processing environments, one is maintained and developed by Findata, the national data access body. Other platforms are developed and maintained by universities, hospitals, and a private actor. As all data processing /research takes place in secure processing environments and one such environment might not work as well for all projects, it is important that there is good availability of different kind of processing environments with different features with a common ground of privacy and security measures in place, including potentially private actors. • **Consider**: the data movement between countries and its further placement in secure processing environments from other countries is not clarified in the current proposal. This is relevant for both placement in one other country as well as placement originating from more than one other country, considering also the needs for anonymised and pseudonymised health data. The same applies for the possibility to communicate with different secure processing environments where data from a single data permit has been allocated.

Permit assessment • *Health data access bodies shall assess if the application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit* (art. 46(1)). • *A health data access body shall issue or refuse a data permit within 2 months* […] *the health data access body may extend the period for responding to a data access application by 2 additional months where necessary* […]. *Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued* (art. 46(3)). • *The data permit shall set out the general conditions applicable to the data user, in particular: (a) types and format of electronic health data accessed, covered by the data permit, including their sources; (b) purpose for which data are made available; (c) duration of the data permit; (d) information about the technical characteristics and tools available to the data user within the secure processing environment; (e) fees to be paid by the data user; (f) any additional specific conditions in the data permit granted* (art 46(6)). • *A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies* (art. 54(2)).	**Permit assessment** • **Consider:** while granting data permits might become a bottleneck whenever they are not assessed promptly, the current wording of automatically granting data access whenever the Health Data Access Body is not on time, might prove unacceptable for some Member States and data holders. Moreover, the proposed construction might reduce the quality of the assessment as the Health Data Access Body will have to rush to handle requests. Sufficient resources and human capital are generally more appropriate measures to ensure efficiency. • **Consider:** enforcing mutual recognition in a stringent manner might lead to competition between the Member States and data holders for the easiest access to secondary use; lacking mutual recognition might lead to a situation where individual Health Data Access Bodies block cross-border applications. How will the EHDS solve the problem of several Access Bodies granting the permit while one refuses to do so? • **Consider:** in case of data access applications based on art. 34, the detailed explanation of the intended use as per art. 45.2(a) might include explanation of the contribution to public health and/or social security of this use, on its risks in terms of privacy of patients and on any commercial use involved. • **Consider:** labelling the health data received via the data permit as 'privileged information'. The disclosure and misuse of such 'privileged information' should be sanctioned. • **Consider:** make use of other tools that could increase the timeliness of the permit assessments, such as: smart use of mutual recognition; the development of European guidelines/code of conducts for the application/ assessment form; an article specifying what the assessment entails and which obligations the Health Data Access Bodies should uphold. • **Option:** the wording for mutual recognition might be altered as follows: *Health Data Access Bodies shall consider relevant permit assessments from*

	other MS authorities. Additionally, a sentence might be added on the pre-requisite of similar datasets (categories) for mutual recognition as the aim is harmonisation and timeliness. • **Option:** in the case where an ethical review is needed prior to grant a data permit, the reviewing processes differ among/within Member States. Mutual recognition of ethical reviews where one ethics review committee accepts and/or builds upon the decisions of other ethics review committees would be a step forward towards mutual recognition of ethical reviews in the EHDS.

Table 3. European Health Data Space Board – Structure	
Formulation in current EHDS proposal	Additional governance considerations
• *The Board shall be composed of the high level representatives of digital health authorities and health data access bodies of all the Member States* (art. 64(1)). • *Other national authorities* [...] *may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate* (art. 64(1)). • *The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure put forward by the Commission* (art. 64(3)). • *Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity* (art. 64(4)). • *The Commission shall chair the meetings of the EHDS Board* (art. 64(6)).	• **Consider:** describing in art. 64 the constellation of the Board, e.g. number of participants per country (what to do when Health Data Access Bodies and Digital Health Authority representatives are from the same institute), voting rules, necessary tasks for the secretariat and the adoption of working programmes. • **Option:** adding an article on the joint formulation of rules by the Commission and the Member States. This alternative might also consider adding a rotating chair or the option for the Member States to select a chair (similar to the selection of the chair for the EHDS Joint Controllership Group). Under this constellation, the Commission will function as a regular member having one or two votes in the highest board. • **Option:** codify a close dialogue with relevant civil society organisations through the creation of a stakeholder/consultation forum. This forum will meet once or twice a year, having an open call for application containing the criteria 'civil society organisation' and 'active in the area of health' (potentially including for-profit actors). The forum might give advice on its own initiative or by the Board on its products, such as the working programmes, codes of conducts, and standards.

Table 4. European Health Data Space Board – Tasks	
Formulation in current EHDS proposal	Additional governance considerations
General tasks of the EHDS Board • [The EHDS Board shall] *Assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation* (art. 65(2)(a)). • *Issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it* (art. 65(2)(b)). • *The Commission shall establish two groups dealing with joint controllership for the cross-border infrastructures provided for in Articles 12 and 52* (art. 66(1)). • *The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures* (art. 66(1)). • *The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces* (art. 66(6)). • *The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them* (art. 66(6)).	**General tasks of the EHDS Board** • **Consider:** specify which guidelines are to be drafted in the near future to allow for the smooth implementation of the EHDS. The documents expected to be drafted by the relevant subgroups might be specified in an annex of the EHDS proposal. At the same time, ensure flexibility to adjust tasks of the EHDS Board according to developments and needs. • **Consider:** define links with developed interoperability standards on terminologies, ontologies and classification systems (HPO, SNOMED CT, ICD-11, etc.) to align interoperability standards. To ensure common understanding, the interpretation would need to be specified for each standard and not just the model/ elements. Here, comprehensive mapping between or alignment of standards to create common data models where possible would support implementation at the operational level at international, national and regional level. • **Consider:** further codify the consultation of the dedicated working group before the drafting of the many delegated and implementing acts (subgroup dealing with Title IV). The relationship between the Commission and the relevant subgroup is sometimes mentioned, but for other articles left unspecified. This gives the unwanted impression that there is a difference between the role of the subgroup concerning some rule-specification. • **Consider:** with regards to the establishment of the joint controllership group, the proposal might want to specify the number of participants per country, voting rights, and how organisations can apply to enter the infrastructure. There is currently no article on the procedure and how the assessment will be carried out.

Minimum data categories • *Data holders shall make the following categories of electronic data available for secondary use* (art. 33): • *(a) EHRs;* • *(b) data impacting on health* […]; • (*c) relevant pathogen genomic data* […]; • *(d) health-related administrative data* […]; • *(e) human genetic, genomic and proteomic data*; • *(f) person generated electronic health data* […]; • *(g)identification data related to health professionals involved in treatment* […]; • *(h) population wide health data registries* […]; • *(i) electronic health data from medical registries for specific diseases;* • *(j) electronic health data from clinical trials;* • *(k) electronic health data from medical devices and from registries for medicinal products and medical devices;* • *(l) research cohorts, questionnaires and surveys related to health;* • *(m) electronic health data from biobanks and dedicated databases;* • *(n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;* • *(o) electronic health data containing various improvements* […].	**Minimum data categories** • **Consider:** as article 33 covers a wide range of data sources to be used within the EHDS, the purposes for processing will have to be delineated accordingly. In this regard, the EDPB and the EDPS likewise recommends to further specify article 34 on processing purposes by strengthening the link between these purposes and public health and/or social security. This might ensure a proper balance between data sharing and (personal) data protection. • **Consider:** before the adoption of the EHDS, there is a need to provide further detail on what is covered under each category as outlined in article 33 of the proposal, like 'genomic data' and 'EHRs' to support EHDS implementation and common interpretations of terminology. Until the proposal's governance options, such as the EHDS Board, are fully operational, the eHealth Network might be invited to work with the European Commission to implement this recommendation. • **Option:** the article on data categories does not make a distinction between the sensitivity of health data sources in relation to the granting of data permits. This structure might prove problematic for some Member States and could be used to block access to certain data types (notably genomic data conform GDPR recital 34 but also biobank data or data from which characteristics like religious orientation might be inferred). Grouping the datasets from article 33 from more to less sensitive and changing the access procedure accordingly might prove fruitful.

Third-country access • *Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation and provide access to data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies* (art. 52(5)). • *The Commission may adopt implementing acts establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of HealthData@EU for the purposes of secondary use of health data*, *is compliant with the Chapter IV of this Regulation and provides access to data users located in the Union to the electronic health data it has access to on equivalent terms and conditions* (art. 52(5)).	**Third-country access** • **Option:** the current proposal does not specify the possibility for third-country non-governmental organisations to become national nodes as part of the EHDS infrastructure, instead solely mentioning international organisations and countries. These organisations possess a wealth of data and valuable human and technical capacity to process health data for research purposes. • **Option:** another important factor not mentioned is the relationship with representatives from the wider global community and EHDS governance. Much of the work being done on health electronic stems from stakeholders in the US. Strong ties with such players due to, for example, formalised observer status in the working groups of the board might reduce the risk of contradictions with the wider global community. Any such industry representation should be counteracted by a strong role for civil society.
Development of standards • *The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability requirements for the secure processing environments* (art. 50(4)). • *The Commission may* […] *set out: common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces* (art. 52(13)(e)). • Technical specifications or existing standards regarding the requirements set out in Chapter IV (art. 65(2)(b)). • *The EHDS Board shall have the following tasks* […] *incentives policy for promoting data quality and interoperability improvement* (art. 65(2)(b)).	**Development of standards** • **Consider:** TEHDAS recommendations based on interviews conducted with several experts from common interoperability standards, including terminologies, ontologies and classification systems, will be ready in December 2022. This document aims to enhance the semantic interoperability of the EHDS, often left unspecified within the current proposal. • **Option:** while the proposal mentions the development of standards to smoothen interoperability, it is not specified how these standards will, in turn, ensure that data flows through the EU without much difficulty. Here, a specification of duties for data holders and users to uphold these standards, akin to the rules mentioned in the EHDS1 for electronic health record services might be fruitful to consider. • **Option:** an article might mention how the Board will promote the implementation of standards, for instance incentivising converging specifications.

Table 5. Cross-border Infrastructure – Structure	
Formulation in current EHDS proposal	Additional governance considerations
• *Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context* (art. 52(1)). • *The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU)* (art. 52(2)). • *Union institutions, bodies, offices and agencies involved in research, health policy or analysis, shall be authorised participants* (art. 52(3)). • *Health-related research infrastructures or similar structures whose functioning is based on Union law* [...] *shall be authorised participants* (art. 52(4)). • *Each authorised participant shall acquire the required technical capability to connect to and participate in HealthData@EU* (art. 52(6)). • *The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure* (art. 52(8)).	• **Consider:** the EHDS services could further prioritise on the specification and definition of the "low-hanging fruits" for secondary data use, i.e., data categories within existing EU-level research infrastructures that fit the description of the use cases. The proposal could foresee using new platforms and services of HealthData@EU to establish links with currently active initiatives in the area of health data, such as 1+MG or DARWIN, and future research projects. While data might be easier to access for research purposes, institutions will often work in siloes. The HealthData@EU infrastructure should function as a new bridge (a node) between these initiatives. • **Consider:** research initiatives might be initiated under the flag of the EHDS, the new structure providing tools to make collaboration easier. This seems partly provided with the wording 'Health-related research' as potential authorised participants of the EHDS. Yet, it ought to be stressed that the HealthData@EU infrastructure implementation should facilitate the integration of further thematic infrastructures to avoid the fragmentation of the (health) data spaces and facilitate collaboration. • **Consider:** under the EHDS, generic services such as identification, authentication and logging could be further standardised, ranging from setting relative generic standards to fully harmonised generic services across all member states.

5. Conclusion and recommendations

The aim of this deliverable was to provide well-established options for governance models for the EHDS, a task part of the broader aim of the TEHDAS project to discuss and formulate sustainable political, legal and technological framework options for the sharing of health data for secondary purposes in (primarily) the EU and other partnered countries. This discussion should not be seen on its own as solely relevant to health policies as it is but one piece within the intricate puzzle of formulating rules for FAIR data sharing in the digital age, formulated within the European Strategy for Data.

The second chapter showed the multitude of interdependent governance elements relevant to the secondary use of health; implemented for some time, like the GPDR; just approved, such as the Data Governance Act; or still very much part of the discussion within the interinstitutional negotiation, e.g., the AI and Data Act. While not mentioned due to being less applicable to the TEHDAS JA, the Digital Services Act and Digital Market Act are likewise part of this broader debate on governance to support the FAIR sharing of data in the digital age. The same is true for the revamping of the two European agencies active in the area of health: EMA and ECDC. The implied complex constellation of rules and organisations, the foundation of the EHDS, will be a challenge for the functioning of EHDS governance.

Adding to the complexity will be the task for the Member States to fit in this patchwork of rules and regulations described above with existing or newly developed national legislation. Future work in TEHDAS will shed light on how the Member States can best prepare for this challenge.

In the third chapter, EHDS governance was approached from an interoperability framework perspective consisting of legislative, organisational, semantic and technical interoperability. It demonstrated the multifaceted challenges for EHDS governance. Each interoperability layer currently has multiple factors that hamper the sharing of health data across the EU. It is thus positive to see that much work has been done to address the identified legislative and organisational issues within the EHDS proposal.

Nonetheless, the nitty-gritty of the technical and semantic challenges still need to be addressed by the specifications of the many implementing and delegated acts of the proposal. Here, the new EHDS Board and the constellation of its subgroups will play a vital role: only by addressing all issues comprehensively, data might be able to flow effortlessly (and safely) across borders. The same is true for the need for constructive interplay between the Commission and the Member states during the development of the delegated and implementing acts within Comitology.

The fourth chapter provided additional governance options and considerations to the current EHDS proposal. These range from alterations to the structure and tasks of the Health Data Access Body at Member State level to make the permit application procedure more harmonised (and specific) amongst the Member States, to additions to the proposed HealthData@EU structure. Another issue was the constellation of the EHDS Board as a central governing actor defining the implementation (standards) of the EHDS. While much

of the structure remains to be formulated by the Commission, attention should be paid to the potential of bureaucratic overgrowth and unclear or overlapping tasks. More specification to the current proposal might be a good way forward, like the number of participants per country, voting rights and groups. Codifying the role of civil society more thoroughly could also provide additional tools to formulate guidelines in line with European values and augment citizen trust. The issue of trust will indeed be a challenge to the well-functioning of the EHDS, discussions surrounding privacy and data sharing omnipresent.

At the same time, however, one issue not discussed within this deliverable is the interlinkage between the primary and secondary use of health data. Within countries, healthcare data gets often documented at the point of care. This data is in scope for the MyHealth@EU structure for the cross-border provisions of care. However, this source data is also in scope of the secondary use of health data, or HealthData@EU, albeit often anonymised and aggregated after the data has progressed through the Data Lifecycle. The choice of semantic standards used when the data gets documented in the process of delivering care will determine wheter it is re-usability at later stages – i.e., for secondary purposes. In general, one could argue that the more detailed the data gets documented at the point of care, the more reusable it will be for secondary purposes. Therefore, aligning semantic standards as much as possible for primary and secondary use will be advantageous for data quality throughout the EHDS. A common semantic strategy in health would be beneficial to that end.

While the first discussions on the EHDS proposal have recently started in Council, many of the discussed issues will be developed more thoroughly by other documents part of the TEHDAS JA. From Work Package 4 on outreach, engagement and sustainability, work on financial sustainability (deliverable 4.3) will be of particular importance as it moves beyond the current discussion on the groundwork (governance system) by providing recommendations on the actual implementation of the EHDS. Financial sustainability will indeed make or break the system. From Work Package 5 on sharing data for health, attention should be paid to deliverable 5.3 on best practices for EU cross-border data exchange. This document will flesh out some of the blanks regarding the many implementing acts of the EHDS proposal. Deliverable 5.2 will provide recommendations on the convergense between the EHDS with existing or newly developed national legislation. From Work Packages 6 and 7 on semantic and technical interoperability, all output will provide valuable tools for developing the legislative and implementing acts. Work Package 8 will provide vital information to improve citizen engagement (data altruism) and increase trust in the EHDS.

In conclusion, this document demonstrated the vast amount of effort already put into the preparation of the EHDS and the amount of work that is still ahead of us to reap the full potential of this envisioned database. We further shed light on the rationale for additional governance options and presented sound alternatives to augment the EHDS, taking into account interoperability layers. This work should establish a governance structure that fosters citizen trust to share data for the common good.

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