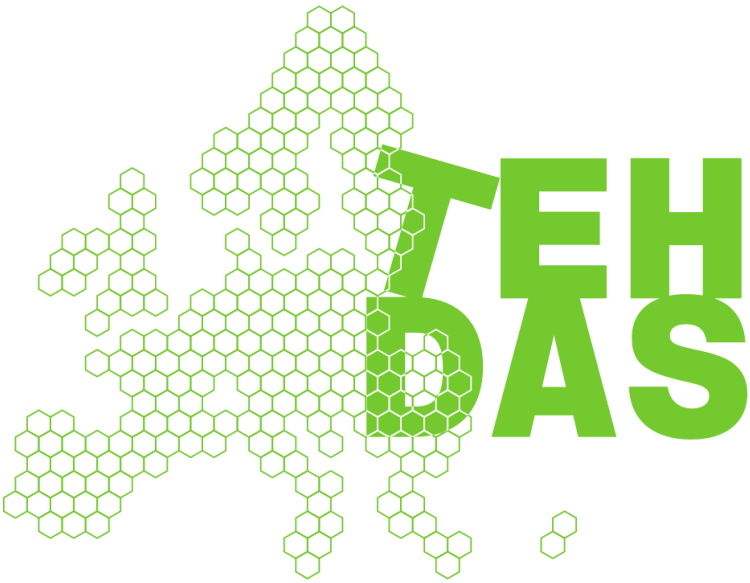

Towards European Health Data Space

Deliverable 5.3

Guidelines document for multi-country data access applications, including mutual recognition and cross-border applications

22 September 2023

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0 Document info

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0.2 Keywords

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Contents

1 Executive summary

As part of the TEHDAS joint action work package 5 (WP5) “Sharing data for health”, led by the Swedish eHealth Agency and by the Dutch Directorate Information Policy of the Ministry of Health, Deliverable 5.3 builds on work carried out within Task 5.3, led by the Health Data Hub. The report aims to provide:

- A summary of the activities carried out in WP5, including the review of the steps in accessing individual-level data for national researchers and researchers from other European Union Member States (milestone 5.4), the development of guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data (milestone 5.5), and the organisation of an online workshop to compile perspectives on multi-country data access applications, mutual recognition and cross-border applications (milestone 5.6).
- Recommendations for effectively enabling projects relying on EU cross-border or multi-country use of health data based on data access and data permit processes in different national settings as well as emerging processes foreseen in the EHDS regulation.
- A summary of the topics that require further study and questions to be resolved.

Even though some efforts have been made to enable cross-border and multi-country projects (e.g., remote access to certain Secure Processing Environments (SPEs), bilateral partnerships), such projects remain difficult to carry out. The process is opaque and is very time consuming for data users. Currently a researcher has analysed unharmonised and largely uncoordinated national authorisation processes, each having their strengths and weaknesses. In addition, only a small amount of the documentation/process is available in English language, conditions for use are not always appropriate for cross border/multi-country projects and the metadata catalogues, when they exist, are usually not interoperable.

The European Health Data Space (EHDS), as foreseen by the European Commission in its legislative proposal presented on the 3rd May 2022, could facilitate access to health data for secondary use purposes, especially for cross-border and multi-country projects, by clarifying, rationalising and streamlining steps in accessing health data in all the Member States of the European Union. By improving access to relevant health data, the EHDS would allow for more and better medical statistical research, evidence based policymaking and innovation, and bring momentum to set the basis of real-world data sharing. In particular, the EHDS legislation provides for:

- Clarification on the governance and creation of Health Data Access Bodies (HDABs);
- Definition of roles and responsibilities of data holders, Health Data Access Bodies and data users
- Harmonised rules and processes for data requests and data access applications, data permit and provision of data to HDABs and data users;
- Ambitious deadlines for authorising access and making data available;
- Pragmatic articulation with the GDPR;
- General framework underlying fees for data access;
- Clarification on data access application & data permit processes in the context of cross-border or multi-country projects.

However, several topics require further study and there are a few questions to be resolved, such as:

- Criteria for setting up HDABs and role of the coordinator;
- Language regime;
- Ethical review;
- Mutual recognition;
- Fees structure and pricing rules;
- Use of Secure Processing Environments (SPEs);
- Standards for semantic interoperability of health data;
- Conditions of access and use.

2 Context

The Joint Action (JA) Towards the European Health Data Space (TEHDAS), helps European Union Member States, associated countries, and the European Commission to develop a common framework for the cross-border secondary use of health data to benefit public health and health research and innovation in Europe. The TEHDAS JA started in February 2021 and runs until 31 July 2023.

TEHDAS JA work package 5 (WP5) “Sharing data for health”, led by the Swedish eHealth Agency and by the Dutch Directorate Information Policy of the Ministry of Health, aims to develop options for governance models for the exchange and secondary use of health data between European countries and to provide recommendations for European countries on planning national legislation to enable cross-border exchange and secondary use of health data.

The activities carried out within Task 5.3 include the review of the steps in accessing individual-level data for national and EU researchers, the development of guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data, and the organisation of an online workshop to compile perspectives on multi-country data access.

The activities carried out in WP5 resulted in three milestones (included in the appendix):

- Milestone 5.4 “Description of steps in accessing individual-level data for national and EU researchers in a selection of centralised systems and decentralised systems”;
- Milestone 5.5 “Guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data”, and
- Milestone 5.6 Compilation of perspectives on multi-country data access applications, mutual recognition and cross-border applications through a workshop approach”.

Five health data platforms have been included across four member states as they were the participants in Task 5.3: Health Sciences Institute in Aragon/BIGAN (IACS/BIGAN) in Spain, Health-RI and Statistics Netherlands, as three structures evolving in decentralised frameworks, and Findata and the French Health Data Hub (HDH) as two national nodes (centralised) for health data access.

3 EU cross-border exchange including data access and data permit processes in different national settings

3.1 Description of steps in accessing individual-level data for national and EU researchers in a selection of centralised systems and decentralised systems (Milestone 5.4)

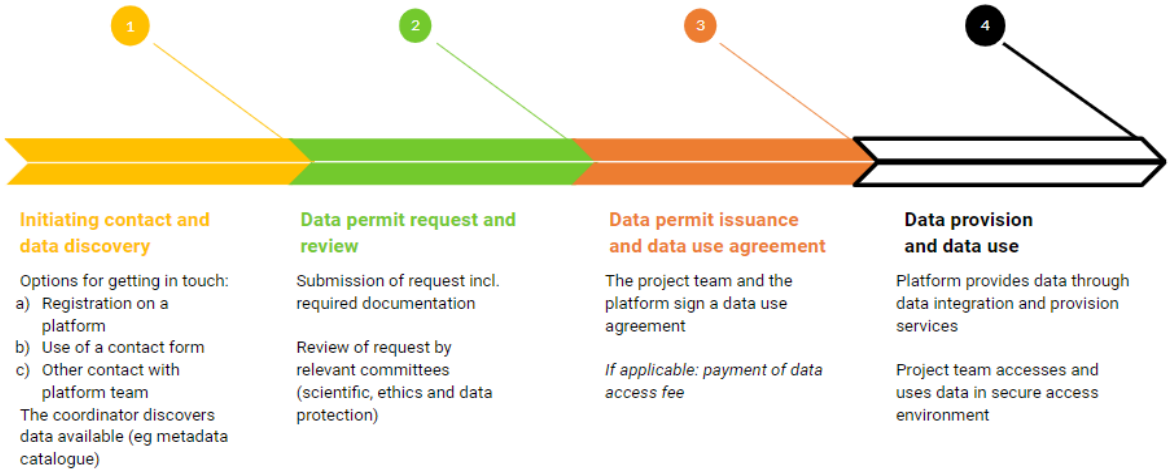
Milestone 5.4[1] aims at describing the steps in accessing health data for national and EU researchers, across a range of different national settings. It also offers a better understanding of the selected institutions' functioning and scientific impact, with a focus on institutional structure, strategic objectives, relationships with data holders and with citizens, as well as the scientific activity and outreach within and outside the health data ecosystem at national, EU and international levels.

To do so, a questionnaire has been designed and sent out to the selected institutions, focusing on 16 topics, including amongst others institutional governance and structure, data types and sources, data access request procedure, process review, permit and data access pricing model. For each topic trends were identified with a more detailed description of whether they represent *ad hoc* or internationally recognised practices.

Steps in accessing health data for the secondary use have been divided as follows:

1) Data discovery;
2) Data permit request and review;
3) Data permit issuance and data use agreement;
4) Data provision and data use.

Figure 1: Steps in accessing health data for the secondary use



[1] https://tehdas.eu/app/uploads/2022/04/tehdas-report-description-of-steps-in-accessing-individual-level-data-for-national-and-eu-researchers-in-a-selection-of-centralised-systems-and-decentralised-systems.pdf

A study of the responses to the questionnaire highlighted the following:

- The different health data platforms federate a myriad of individual-level data sources, including medico-administrative data, hospital registries, EHRs, and even biobank data (in the case of Health-RI).
- National researchers are unanimously eligible to access health data in the four selected countries/regions.
- Health data access procedures take place exclusively online.
- The committees identified as directly involved in the review process are the following: 1) Ethical/ scientific committees; 2) Steering entity (a governing body which assesses the requests) 3) A data protection agency. Only Findata and IACS/BIGAN centralises completely the processes for two or more data source requests.
- A data use/access agreement has to be signed between the authorised user and the platform.
- Fees apply when it comes to one or all of the following services: review of the data permit request; authorisation of access (permit issue); data extraction services; additional fees applied by data holders; use of the virtual working environment; use of available technological capabilities.

The institutional differences explain some of the differences in engaging and collaborating with data holders. However, notwithstanding differences in the entities legal form and minor differences, the process of reviewing and granting access is quite homogeneous. The assessment of the five entities also highlights the need to further strengthen peer-to-peer cross-border collaboration.

To conclude, the study of the health data access procedures in different national/regional contexts demonstrates the importance of a one-stop shop for health data in national settings and the need to foster the implementation of national nodes and centralised health data access review processes.

3.2 Guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data (Milestone 5.5)

Milestone 5.5[2] proposes and details six major steps to follow to initiate a bi- or multilateral partnership agreement between structures wishing to share health data for secondary use, with a focus on cross-border data sharing partnership.

1) Establishing contact between prospective partners;
2) Initiating the partnership;
3) Framing the partnership;
4) Legal work and signature of the partnership agreement;
5) Defining a partnership comitology;
6) Defining dissemination and communication activities.

In the case of data sharing projects, a major aspect to define when framing the partnership is the intended data sharing scope under the partnership (e.g. unilateral access to one of the other national data platforms involved, mutual access to all national platforms involved, query on the metadata catalogue, etc.) as it will significantly impact the rest of the process.

[2] Guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data, https://tehdas.eu/app/uploads/2022/04/tehdas-guidelines-for-a-peer-to-peer-and-cross-border-partnership-for-the-secondary-use-of-health-data.pdf

The partnership should include the definition of the data model and study protocol and identify the applicable regulatory process for each partner. As the data authorisation process and associated timeline can differ significantly from one country to another, partners should provide an overview of the regulatory process. Finally, the agreement should define technical tools and capabilities.

There are several types of legal partnership agreements. The most appropriate agreement form strongly depends on the nature of the partnership that will be concluded between the different parties. Legal partnership agreements include Data Sharing Agreement (DSA), Memorandum of Understanding (MoU), Memorandum of Agreement (MoA) and European partnerships such as European Union Consortiums funded by the European Commission, European Research Infrastructure Consortium (ERIC) or European Digital Infrastructure Consortium (EDIC).

Milestone 5.5 also identifies the main obstacles encountered in establishing a cross-border partnership and hindering cross-border secondary use of health data: complex regulatory procedures and pricing models across the Member States, fragmentation of the information systems used in healthcare institutions, lack of standards, poor data quality (especially for data that were not originally collected for research purposes); and insufficient funding.

With the implementation of the EHDS, these partnerships will be based on the rules for health data sharing laid down in the regulation, and therefore become either superfluous or easier to frame and launch.

3.3 Compilation of perspectives on multi-country data access applications, mutual recognition and cross-border applications through a workshop approach (Milestone 5.6)

Milestone 5.6[3] presents a synthesis of exchanges and discussions held during a workshop on “Current governance processes for the secondary use of data and perspectives under the EHDS”, held on 29 March 2023, as well as a summary of the outcomes and recommendations.

The workshop brought together representatives from Finland, France, the Netherlands, Spain, Sweden and the European Commission, and covered the different types of stakeholders (data users, data holders, research ethics committees, governmental authorities, and health data access bodies).

Its aim was twofold: firstly, to get an overview of the steps in accessing individual-level data for national and EU researchers in a selection of centralised and decentralised systems in cross-border and multi-country contexts, and secondly to evaluate the impact of the proposed EHDS regulation. In particular, it aimed to share perspectives on current governance processes (best practices, pain points), their impact on the realisation of cross-border and multi-country projects as well as their potential evolution under the proposed EHDS regulation; and to verify that all stakeholders have a shared understanding of how cross-border and multi-country applications would work under the proposed EHDS regulation and what aspects may still require further clarification.

Even though some efforts have been made to enable cross-border and multi-country projects (e.g., remote access to certain Secure Processing Environments (SPEs), bilateral

[3] Compilation of perspectives on multi-country data access applications, mutual recognition and cross-border applications through a workshop approach, to be published

partnerships), such projects remain difficult to carry out today. Indeed, The process is opaque and is very time consuming for data users, as a researcher currently has to go through uncoordinated national authorisation processes, each having their strengths and weaknesses. In addition, only a small amount of documentation/processes is available in English language, conditions for use are not always appropriate for cross border/multi-country projects and the metadata catalogue, when they exist, are usually not interoperable.

The European Health Data Space (EHDS), as foreseen by the European Commission in its legislative proposal presented on the 3rd May 2022, could allow for more and better medical statistical research, and bring momentum to set the basis of real-world data sharing. In particular, the EHDS legislation provides for:

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- Standards for semantic interoperability of health data;
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4 Recommendations for best practices for EU cross-border exchange

The activities carried out in T5.3 have highlighted several areas requiring further study. Some of these topics are being investigated in the framework of the HealthData@EU Pilot project[4], bringing 17 partners together, including national data platforms, European agencies, research infrastructures, international organisations and research networks. The pilot will test the EHDS for secondary use user journey, and therefore work on data discovery and prestudy, data access application, data preparation and use of data.

4.1 Overall recommendations

The overall governance and roles and responsibilities of the actors involved should be further clarified. The draft regulation provides for an overall framework with the

[4] https://ehds2pilot.eu/

distinction of three major roles: health data holders, HDABs and health data users. However, several issues remain open, such as the possibility for the Member States to designate several HDABs, without specifying criteria, or guidelines for these bodies; the scarcely defined role of the coordinator of HDABs, and of the national contact point despite the long list of tasks for HDABs foreseen in Article 37(1); or the possibility for Member States to adopt simplified procedures. In order for the EHDS to work well, the governance must remain clear and the regulation should provide for a coherent and efficient division of roles and responsibilities of data holders, HDABs (and where applicable, the national coordinator of HDABs and the national contact point) and data users.

One main idea behind setting up HDABs is to have a unique point of contact for data holders and data users facilitating their role within accessing or providing access to health data. In particular, data users require guidance in the data access process, a spokesperson for interactions with institutional actors to address difficulties encountered. Data holders also look for guidance with regards to measures related to the opening of data such as setting up health data warehouses.

Also, other actors (e.g. patient associations) would benefit from having a single actor to turn to express their needs and concerns and to weigh in on the operationalisation of the EHDS. As countries will be faced with important choices around the designation and set-up of HDABs, specific criteria for such bodies, guidelines and ad-hoc support might help them in these choices. While countries will most likely be free in their choice, designating several HDABs will come at a cost in terms of complexity and resources, as the proper performance of the tasks listed in Article 37(1) will require a critical mass of skills and financial resources, which risks not being available in several HDABs.

A multiplicity of actors with similar roles risks diluting the accountability of actors and reducing the readability for users. For instance, it seems crucial to keep a clear difference between the role of the HDAB and the role of a data holder as a provider of access to health data. In Article 49, the proposed regulation already provides for the possibility for a data holder to make available the data it holds, even in the case of federated actors is federated (e.g., a grouping of healthcare facilities). Given these actors under Art. 49 of the EHDS regulation would be able to make data available, it does not appear necessary to grant these data holders the status of a HDAB, which would carry the risk of confusing stakeholders and creating additional complexity when carrying out the tasks under Article 37(1).

Given the number of tasks assigned to the HDABs, Member States should be aware that each HDAB will require significant human, technical and financial resources, and adequate premises and infrastructure. The precise impact of these choices would depend on the tasks and perimeter attributed to each HDAB but in any scenario having more than one HDAB will require additional technical and human resources, for instance to:

- set up additional secure data transfer channels between data holders and HDABs;
- developing or connecting to HDAB business capabilities (metadata catalogues, data application submission and management systems, project registers, etc.);
- recruit staff to fulfil HDAB tasks requiring specific competencies (e.g. data access procedures and legal requirements, data management and technical skills, etc.).

For countries setting up more than one HDAB, additional efforts will be required to support the ecosystem. One way of achieving that, could be by strengthening the role of the Coordinator of HDABs.

Strengthen the role of the Coordinator in the proposal

In the EHDS proposal, the role of the coordinator of HDABs is scarcely defined. Given the list of tasks of the HDABs, a clearer definition of the role of the coordinator in countries where more than one health data access body is established seems of fundamental importance. This could be reflected by specifying in the legislation (or a recital) that beyond coordinating requests with HDABs, the role of the coordinator could be specified for each of the tasks under Article 37(1). Depending on the task, the coordinator could either: exclusively carry out the task; coordinate all national relevant HDABs; centralise activities and inputs from other HDABs or; harmonise activities among HDABs.

In addition, the legislation could foresee that the Commission provides guidelines for what roles the Coordinator should play in countries having more than one HDAB for each of the tasks of Article 37(1). The legislation could draw on the table summarising the discussions held during the workshop on "Current governance processes for the secondary use of data & perspectives under the EHDS", held on 29 March 2023 and included in milestone 5.6, where participants exchanged on the role and responsibilities of the coordinator, the HDABs and the data holder for each of the tasks under Article 37(1).

Such a strengthened role could enable a more harmonised and better coordinated action of HDABs. It could also enable other stakeholders such as data protection authorities, health data users and holders as well as civil society to navigate the system without multiplying the discussions on similar topics and avoid inconsistent rules and procedures.

Finally, additional information could be provided on the designation of the National Contact Point for the secondary use of data, defined in the draft regulation as "organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States under the responsibility of the Member States". For countries setting up more than one HDABs and where a coordinator will be designated, it would be appropriate to entrust the coordinator with the role of National Contact Point for the secondary use of data. This would reduce the number of steps and actors involved in the context of cross-border or multi-country applications and bring more readability for the data holders and users.

Additional funding appears crucial to allow countries to proceed and work towards the ambition of the EHDS. Additional investments in the digital stream of the EU4Health programme but also topics in other streams (e.g., cancer) involving the secondary use of health data and especially to support data holders to make data available for secondary use appear as a prerequisite for making the EHDS a reality.

The regulation should also clarify pricing rules and adopt a full cost logic for a fair sharing of costs around the secondary use of health data. In the absence of sustainable financing of health databases, access fees can allow health data holders and HDABs to make investments into the databases and the services provided. For data holders, being able to recover part of the cost to collect (and possibly improve) the data, and not only the cost of making the data available for the study, would be an incentive to invest in data collection and data quality. As far as the health data access body is concerned, fees covering costs to prepare, combine and make the data available could be a contribution to the cost of these organisations. The subject of access fees merits further discussion at the European level and should at least be subject of European guidelines.

Even though some efforts have been made to make the processes and documentation understandable for data users, **language remains an obstacle for health data sharing for EU cross border projects.** For instance, metadata catalogues, as well as documentation and information are often only available in the local language.

This is an area where concrete solutions should be implemented. For all steps in the user journey but in particular for data discovery and data access application, **documentation, data user support services and training should be available to all.** A few examples below:

- Data discovery: translation of the metadata catalogues in English or via an automatic tool (for instance via eTranslation, the European Commission's Machine Translation system)
- Data access application: possibility to apply in English, application form translated in English, translation of trainings and support services in English.

4.2 Recommendations on data discovery and prestudy

Milestone 5.1 and 5.2[5] have identified the lack of findability, the lack of an inventory listing all kinds of datasets (including metadata catalogues) that can be made available as one of the main barriers to the re-use of health data. In the national settings investigated, an exhaustive metadata catalogue seems to be rather the exception than the rule, even though several countries are undertaking efforts to build or consolidate a metadata catalogue.

An additional issue is the lack of standardised and interoperable metadata catalogue at the European level. The HealthData@EU Pilot project aims to **develop a descriptive metadata standard (Health DCAT-AP extension)** respecting the FAIR principles[6] and user needs of the EHDS. While this work will start as the basis for a catalogue of dataset descriptions, HDABs and other authorised participants can extend this by including information at the variable level and thus pave the way for a more complete data discovery process. Article 55 of the EHDS regulation foresees that an implementing act should provide the minimum information elements data holders should provide to HDABs and thereby codify such a standard. TEHDAS WP6 has also made recommendations on this topic as part of Deliverable 6.3[7], distinguishing the need of a generic metadata standard for some information and for domain-specific metadata standards.

The EHDS draft regulation provides a response to this issue of data discovery as it foresees the establishment of national metadata catalogues that could be consulted through an EU dataset catalogue portal. Providing a dataset description to HDABs will be a legal obligation for data holders under the EHDS, which should lead to exhaustivity. As highlighted in previous work as well as milestone 5.6, the ability for researchers to discover what data can effectively be available for their projects is a major enabling factor for cross-border and multi-country projects. The more granular the information available in these catalogues is, the more researchers will be able to assess whether a database is actually appropriate for their project. While a high-level description of databases would already improve findability, it would not be enough to enable researchers to verify the appropriateness of a dataset for their research question. For that, additional information such as variable-level information would be required. It has been highlighted that information included in the dataset description should not be limited to the dataset itself but also cover useful information such as the process and conditions for accessing it, and any other information useful to support the data user in the feasibility assessment. This aspect is covered by the EHDS draft regulation, as Article 55

[5] https://tehdas.eu/results/tehdas-identifies-barriers-to-data-sharing/
[6] The FAIR principles aim at making data Findable, Accessible, Interoperable and Reusable.
[7] TEHDAS deliverable 6.3, report on "TEHDAS Data Quality Framework" (to be published)

foresees that the dataset description includes the “conditions for making electronic health data available”.

Therefore, in the context of the current establishment of metadata catalogues it is recommended to foresee the possibility of further evolving these so that they could be extended to cover for instance variable-level information once resources are available for that.

In addition, the proposed EHDS regulation also foresees the establishment of a Data quality and utility label that should be available for certain datasets having received European or other public funding. Such a label, if well designed and implemented, could be of additional help to future data users. It appears essential to integrate it within the national metadata catalogues as well as the EU Datasets catalogue.

4.3 Recommendations on data access application

The draft EHDS regulation foresees that **the European commission**, by means of implementing act, **proposes a common data access application form used by all countries**, drawing from the experience of the HealthData@EU Pilot project, which is currently developing a single and harmonised data access application form that will allow to submit applications to data from several countries through that harmonised form through a single portal. While the HealthData@EU Pilot project has to deal with the heterogeneous national prerequisites and processes, the EHDS regulation provides a common framework applicable in all countries, including a list of items to submit as part of data access applications or data requests, which would make it easier to set up and agree such a common application form as part of a future implementing act and thus harmonise and streamline the data application process. In this context, the HealthData@EU pilot project is testing a process whereby the applications would be submitted through a European portal and dispatched from there to HDABs rather than submitted to one HDAB who would need to dispatch it to other relevant HDABs. This could make the process easier and avoid delays in data permit delivery to users.

The regulation does not address the issue of ethical or scientific committees, and their establishment and role seem to be left at the discretion of the Member States. In the four national settings studied in T5.3, ethical or scientific committees are usually involved, however their role is quite heterogeneous. Within Spain, regional Research Ethics Committees recognize their rulings mutually. For the countries deciding to have such ethical and scientific committees in accordance with national law, **there could be an exchange of best practices and maybe even guidelines on the functioning of ethical or scientific committees**.

In addition, the HDABs concept of mutual recognition would need to be further refined in order to be operationalised. Questions in that context could be for instance what part of the process the recognition would cover, how it would affect the responsibility of the HDAB applying the mutual recognition principle, what common rules and requirements the HDABs could set up for considering mutual recognition.

Finally, **the European Commission could**, by means of implementing acts, **define general conditions of use and develop a model for data use agreements** between HDABs and data users, drawing from the work carried out in the HealthData@EU Pilot project.

4.4 Recommendations on data preparation for use

The regulation should include a stronger focus on data interoperability and documentation. Indeed, the text does not speak explicitly enough about standardisation of databases and standardisation of national metadata/catalogues, although this is an essential element to make the EHDS work. In this context, another TEHDAS deliverable has proposed "data holders to implement a layer of semantic interoperability using widely adopted standards [...]. As a preferred framework, in the short run, data holders should follow an incremental approach to progressively map their regular controlled vocabularies to international general and domain-specific ontologies. The European Commission should support continuous dialogue on this governance mechanism, [...]."

To realise the full potential of secondary use of health data and especially in a cross-border or multi-country context, clearer rules and more investments in semantic interoperability seem necessary. The HealthData@EU pilot project currently elaborates on this question based on a number of multi-country research use cases. Based on these, the project will provide feedback on and guidelines for data standards to address semantic interoperability, including data quality assurance and the definition of security prerequisites for transfer.

4.5 Recommendations on Data access provision and data use

A clear vision of how SPEs[8] that would be used in the case of cross-border and multi-country projects, is required to resolve open questions. The regulation does not clearly specify whether there is a legal basis for pooling data within a single SPE and therefore effectively transferring data across borders which for now is explicitly forbidden and excluded by some countries. The regulation proposal only foresees that at the request of more than one country, the data could be analysed in a SPE provided by the EC. Would such a SPE need to be one developed by the EC or could it be a SPE by an external provider or a national SPE that fulfils certain requirements or has undergone a certain review process? Also, more clarity on how the requirements of Article 50 of the EHDS regulation will be articulated with pre-existing national technical and security requirements for the hosting and manipulation of pseudonymised health data is required. The same applies to rules for the transfer of health data before it is made available in a SPE. Given the multiple questions around the place of SPEs, the responsibilities of the actors involved and the requirements they need to fulfil merit in-depth discussion to make HealthData@EU work but are beyond the scope of this report.

In addition, the EHDS should not restrict the secondary use of health data beyond the provisions of the GDPR, which provides for a sufficient and balanced framework. Yet, **the issue of information to citizens should be taken into account.** With regards to information, the approach proposed by the draft regulation to establish public project registers (transparency registers) at the level of HDABs, on top of information provided by data holders to citizens, appears to be feasible. HDABs should however not be required to provide individual information about every reuse to individuals, which would be disproportionate, potentially overwhelm individuals, not taking into account their specific situation (e.g., a sick person not wanting to be reminded continuously about their health status) and involve more processing of individuals' data. It would be important, though, that even if there are several HDABs in a country, an exhaustive register exists at the national level to allow citizens to retrieve that information at a single place. In addition, the content of the register should be understandable to citizens and include sufficient and relevant) information in a structured

[8] Secure Process environment requirements are listed in Article 50 of the EHDS draft proposal.

format (e.g. table with objectives, data used, methods, duration, etc.) and could ideally be defined as a European standard.

Finally, the EHDS should balance the individual's rights and collective interests to enable processing for certain purposes (e.g., pharmacovigilance by supervisory authorities) and guarantee a proper monitoring of the exercise of the data subjects' rights. This would need to be considered if the EHDS regulation includes an opt-out mechanism different from the GDPR.