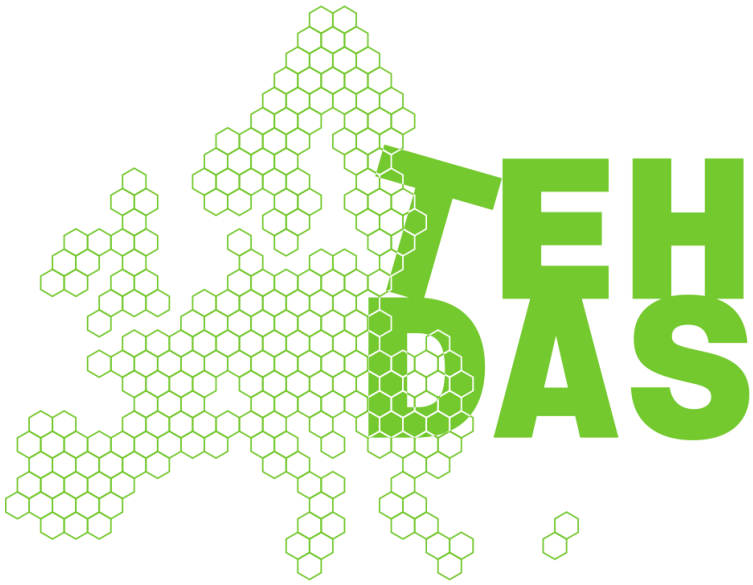

Towards European Health Data Space

Milestone 5.6

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

5 July 2023

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0 Document info

0.1 Authors

Author	Partner
Marianne Benderra	Health Data Hub
Mario Jendrossek	Health Data Hub
Peija Haaramo	Findata
Ramón Launa	Instituto Aragonés de Ciencias de la Salud
Coen van Gool	RIVM *Rijksinstituut voor Volksgezondheid en Milieu*): Dutch Institute for Public Health and the Environment
Jan-Willem Boiten	Health-RI
Michel Silvestri	Swedish eHealth Agency

0.2 Keywords

Keywords	TEHDAS, Joint Action, Health Data, Health Data Space, Data Space, data sharing

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1 Introduction

1.1 Context

The Joint Action (JA) Towards the European Health Data Space (TEHDAS), helps EU Member States, and the European Commission (EC) 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 1 August 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.

As task 5.3 lead, the Health Data Hub organised an online workshop on “Current governance processes for the secondary use of data & perspectives under the EHDS”, on March 29, 1pm-4pm CET.

The present document (“Compilation of perspectives on multi-country data access applications, mutual recognition and cross-border applications through a workshop approach”) presents a synthesis of exchanges and discussions held during the workshop as well as a summary of the outcomes and recommendations.

1.2 Aim of the workshop

The aim of the workshop was twofold:

- 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 (Spain, France, the Netherlands, Sweden, Finland) especially in crossborder and multi-country contexts; and
- To evaluate the impact of the proposed EHDS (European Health Data Space) 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;
- 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.

1.3 Agenda

Time		Session
13h00	**15min**	**Introduction**
13h15	**40min**	**Session 1: Crossborder and multi-country data access applications in the current legislation**
	20min	1.1. Presentation of the "as-is" situation ● Data discovery ● Data access application, permit and data provision ● Simplified procedures ● Contractualisation ● Fees
	20min	1.2. **Discussion -** Best practices, pain points and how the current situation impact cross-border and multi-country projects
13h55	***1h30****	**Session 2: Crossborder and multi-country data access applications under the EHDS regulation**
	20min	2.1. Presentation of foreseen processes for cross-border and multi-country data access application ● Relevant EHDS regulation provisions ● Foreseen processes for a cross-border and a multi-country data access application ● Foreseen processes under Art. 48 and Art. 49 (access without a permit and access at the level of a single data holder)
	70 min	2.2. **Discussion -** Shared understanding of the regulation ● Discussion on the governance and mechanisms for the secondary use of data ● Distribution of roles and responsibilities for Art.37 tasks
15h25	***30min***	**Session 3: Perspectives and recommendations for a successful implementation of the EHDS regulation Discussion**
15h55	***5min***	**Closing**

1.4 Participants

The workshop brought together representatives from:

Country	Organisation	Type of stakeholder
Finland	Findata	HDAB

Country	Organisation	Type of stakeholder
	Finnish Institute for Health and Welfare (THL)	Data user / data holder
	Social Insurance Institution (Kela)	Data holder
	Pharma Industry Finland	Data user
France	CESREES	Research Ethic Committee
	Health Data Hub	HDAB
	University Toulouse III	Data user
The Netherlands	Statistics Netherlands / CBS	Data holder, HDAB
	Health-RI	Data holder, HDAB
	RIVM	Data user
	Ministry of Health	Other
Spain/Aragon	IACS	Data holder, data user, HDAB
	CEICA	Research Ethics Committee
	Ministry of Health	Governmental actor
Sweden	SEHA	Governmental agency/authority
	GMS/Swe government	Data holder, Governmental actor
European Commission	DG SANTE	EU

2 Session 1: Crossborder and multi-country data access applications in the current regulatory framework

2.1 A crossborder or multi-country data access request today

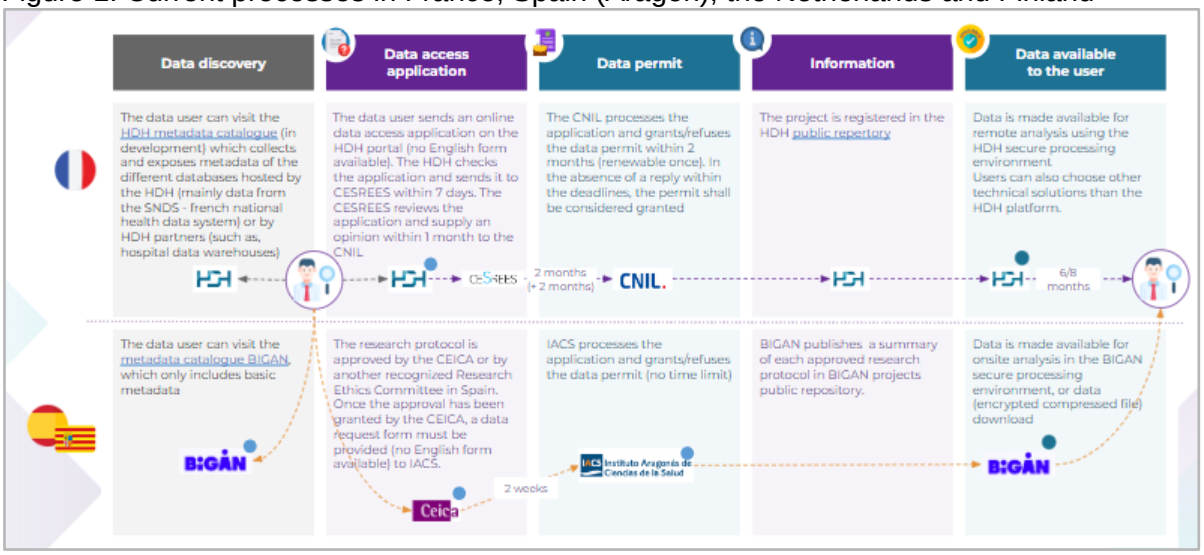
2.1.1 Current processes in France, Spain (Aragon), the Netherlands and Finland

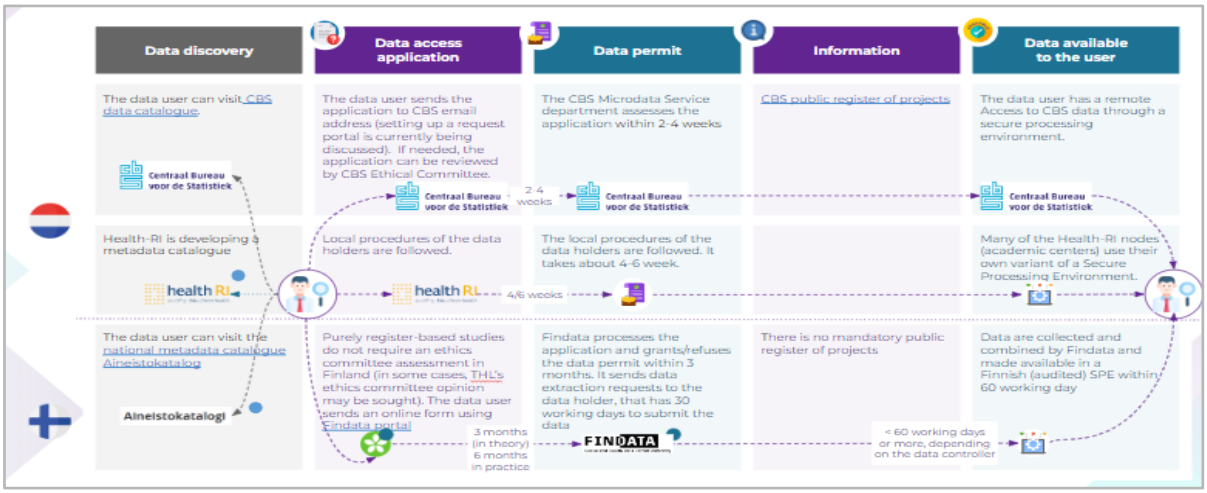
The governance processes studied include selected centralised (Finland, France) and decentralised (The Netherlands, Spain) systems, a choice dictated by the composition of TEHDAS Task 5.3 participants, namely Finland (Findata), France (Health Data Hub, Toulouse University, Orphanet), the Netherlands (CBS and Health-RI), and Spain (IACS).

One major difference between the countries lies in the degree of centralisation of the decision on data access. The systems considered below range from largely centralised access decisions to largely decentralised systems.

As for the similarities, it can be noted that there is regularly a formal application procedure involving certain supervisory bodies. Furthermore, most nodes provide for time limits in handling applications and the provision of an exhaustive metadata catalogue seems for now to be rather the exception than the rule.

Figure 1: Current processes in France, Spain (Aragon), the Netherlands and Finland





France

Step	Process
Discovery	The data user visits the HDH metadata catalogue (available in French, in development) which collects and exposes metadata of the different databases hosted by the Health Data Hub (mainly data from the SNDS - French national health data system) or by Health Data Hub partners (such as hospital data warehouses)
Data access application	The data user sends an online data access application on the HDH portal (no English form available) The HDH checks the application completeness and sends it to CESREES within 7 days The CESREES (independent ethical and scientific committee, established by the Ministry of Health and the Ministry of Research) checks that the purpose of the study is relevant and of "public interest", that the data requested is appropriate and that the proposed methodology is robust, and supplies an opinion within one month to the Cnil (the opinion is not binding)
Data permit	The application is transmitted to the the French Data Protection Authority Cnil (Commission on Information Technology and Liberties, French Data Protection Authority) for authorisation. The Cnil mainly verifies that individual liberties are respected and that adequate security measures are put in place, and grants or refuses the permit within 2 months, renewable once. The permit is considered granted if no answer is given within the deadline

Step	Process
Information	All projects are registered in the HDH Public project register
Data available to the user	Data in a pseudonymised format is made available for remote analysis using the HDH secure processing environment. The data cannot be downloaded. Users can also choose other technical solutions than the HDH platform. It usually takes between 6 and 8 months to make the data available mostly related to time taken by data holders to extract the data.

Spain / IACS (Health Sciences Institute in Aragon)

Step	Process
Discovery	The data user visits BIGAN metadata catalogue, which only includes basic metadata and is partially available in English.
Data access application	The data user sends the data access application via a central request portal. There is no data application available in English yet. Documentation describing the permit request process is available on IACS website The research protocol is approved by the CEICA (Comité Ético de Investigación Clínica de Aragón) or by another recognised Research Ethics Committee in Spain (mutual recognition) Once the approval has been granted by the CEICA, a data request form must be provided (no English form available) to IACS.
Data permit	IACS processes the application. There is no deadline for processing the request. Taking into account data sensibility, tacit permit is not permitted in BIGAN. Instead, express approval is needed. Most data requests are served within a month of the request. depending on the workload and meeting schedules of the IACS Biocomputing Unit supporting BIGAN data request processing
Information	The data user is provided with information on next steps upon completion of each procedure. BIGAN publishes a summary of each approved research protocol in a public repository

Data available to the user	Data is made available for onsite analysis at the BIGAN secure processing environment (direct remote access to the BIGAN SPE by the user currently under testing ie. development phase), or pseudonymised data (encrypted compressed file) download per user´s project.

The Netherlands

Step	Process	
	CBS	**Health-RI**
Discovery	The data user visits the CBS (Statistics CBS (Statistics Netherlands) data catalogue. The catalogue is currently only available in Dutch, but an English version is planned.	Health-RI is developing a metadata catalogue (currently only available for COVID data) and is managing the BBMRI biobank metadata catalogue. Discovery services are available in English here.
Data access application	The data user sends the application to CBS email, in Dutch or in English, (setting up a request portal is currently being discussed). If there are any doubts about accepting a study on ethical grounds, the application can be reviewed by the CBS Ethical Committee.	The data user can send a request in English. A specific application is available, but only used for a limited number of resources.
	Apart from CBS and Health-RI, there are many nodes for access, and the researcher can go directly to the source in many instances, i.e. to the data holder. In many instance a Data Access Committee is involved	
Data permit	CBS microdata service department assesses the application, within 2 to 4 weeks.	The local procedures of the data holders are followed. It usually takes about 4-6 weeks.
Information	The research results must be made public on the website CBS public register of projects	

Step	Process	
	CBS	**Health-RI**
Data available to the user	The data user has a remote Access to CBS data through a secure processing environment (SPE)	Depends on requirements of data holders. Many of the Health-RI nodes use their own variant of a SPE, “Digital research environment”

Finland

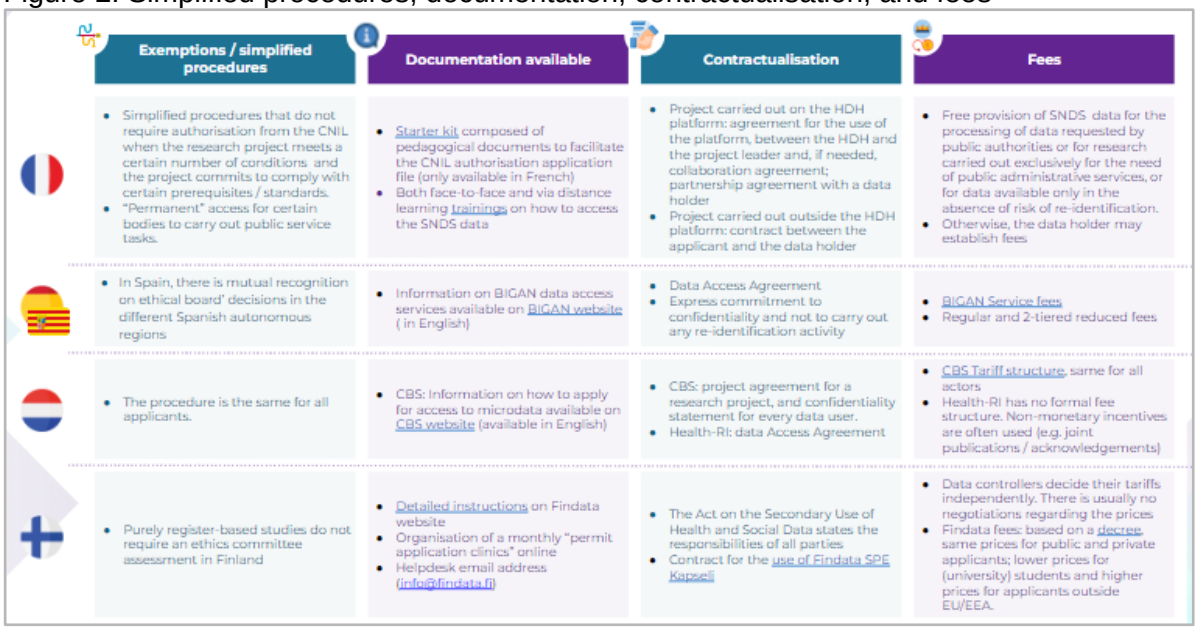
Step	Process
Discovery	The data user can visit the Finnish national metadata catalogue Aineistokatalog, which is not yet exhaustive, and partially available in English.
Data access application	Findata is the national data permit authority and as such is the exclusive contact point. The data user sends an online form using Findata portal (available in Finnish, Swedish and English). Purely register-based studies do not require an ethics committee assessment in Finland (in some cases, THL’s ethics committee opinion may be sought).
Data permit	Findata processes the application and should grant or refuse the data permit within 3 months, based on the Act for Secondary use Findata checks the application from a legal viewpoint, but does not conduct any scientific assessment of the research plan. In reality it almost never refuses the permits.[1] In practice there is a queue/waiting time (currently about 3 months) before the handling starts, then it takes about 2 months for the data application to be processed. Findata then sends data extraction requests to the data holder that has 30 working days to provide the data.
Information	There is no mandatory public register of projects

[1] https://findata.fi/en/

Step	Process
Data available to the user	Data is collected and combined by Findata and made available in a Finnish (audited) SPE within 60 working days. It usually takes less than 60 working days, depending on the data controllers. If the data extraction process has several steps (e.g. cohort from one data controller, then control group from another, and then the outcome data from yet another data controller) it can take more than 60 days.

2.1.2 Other relevant topics

Figure 2: Simplified procedures, documentation, contractualisation, and fees



Simplified access

Alongside the standard application procedures that have been developed, some Member States allow for a number of derogations.

For instance, France has established, on the one hand, simplified procedures that do not require authorisation from the CNIL when the research project meets a certain number of conditions and the project commits to comply with certain prerequisites / standards[2], and on

[2] There are different simplified procedures, called reference methodologies (RM). For one of them, the conditions relate to the project leaders concerned (health establishments and hospital federations), or the actors making the data available (the Technical Agency for Information on Hospitalisation (ATIH)). For another RM, the conditions relate to the project leaders involved (health care institutions) or the actors making the data available (ATIH). In addition, the study must be implemented by a research

the other hand, “permanent” access to the SNDS for certain bodies to carry out public service tasks. The list of organisations having such a “permanent” access is listed in Art. R1461-12 of the Public Health Code, and can be amended.

In Finland, purely register-based studies do not require ethics committee assessment.

In Spain, there is mutual recognition of ethical board’ decisions in the different autonomous regions.

In contrast, the procedure is the same for all applicants in the Netherlands, without simplified mechanisms.

Documentation available

Documentation in English is usually available on the organisation websites, to describe and facilitate the process on how to apply for access to health data:

- Information on BIGAN data access services available on BIGAN website;
- Information on how to apply for access to microdata available on CBS website;
- Detailed instructions on Findata website.
- To provide more information on permit application, Findata also organises monthly “permit application clinics” online and manages a helpdesk (info@findata.fi).
- As for France, the HDH has developed a starter kit composed of pedagogical documents to facilitate the CNIL authorisation application file, and has designed both face-to-face and distance learning training on how to access the SNDS data. However,both the starter kit and the training are only available in French.

Finally, the possibility to write an application in English is rather the exception than the rule.

Contractualisation

In France, the HDH is a unique gateway. As such, the nature of the contracts depends on whether the project is carried out on the HDH platform or not. In the first instance, the agreement for the use of the technological platform is signed between the HDH and the project leaders. If specific support from the HDH is offered,a collaboration agreement is also signed. In the second instance, a contract is signed between the applicant and the data holder. Furthermore, partnership agreements are signed with the data holder if the data holder wants to put a copy of its database in the catalogue (copy of the database in the HDH system from which extractions can be made).

The contractual framework is quite similar in Spain/Aragon and in the Netherlands, as they involve data access agreement and express commitment to confidentiality.

Finally, in Finland the responsibilities of all parties are stated in the Act on the Secondary Use of Health and Social Data. Besides, a contract for the use of Findata SPE Kapseli must be signed.

Fees

Rules about fees and credits vary to a great extent.

laboratory or a research office that has made a commitment to comply with the CNIL and an audit must be carried out on the purposes of the use of the results of the study by the project leader.

In France, the concrete application and the exact methods of calculating possible royalties/fees is still under discussion. In order to establish a framework, the French Strategic Health Data Committee launched a working group on the subject, under the impetus of the Health Data Hub, which provides the secretariat. The objective is to jointly deal with the terms of pricing but also the financing models necessary to manage to maintain databases and infrastructures whose access will remain largely free. Medico-administrative SNDS data for the processing of data requested by public authorities or for research carried out exclusively for the need of public administrative services are provided for free. As for accessing other data, the data holder may establish fees.

The Aragon region, BIGAN has established Service fees. and proposed reduced fees.

In The Netherlands, CBS has established a Tariff structure (which is the same for all actors) whereas Health-RI has no formal fee structure. As for the latter, non-monetary incentives are often used (e.g. joint publications / acknowledgements).

Finally, in Finland, data controllers decide their tariffs independently and there are usually no negotiations. As for Findata, the fees for carrying out the data permit process are based on a decree. The same prices apply for both public and private applicants. However, fees are lower for University students and higher for applicants outside EU/EEA.

2.1.3 Discussion

Cross-border project and access given to international researcher

Data is accessible to international researchers in France, Finland, the Netherlands (for researchers from institutions located within the European Economic Area (EEA) or in a country with an adequacy decision) and Aragón.

Categories of data in scope for secondary use of health data - genetic data and samples

- The EHDS regulation proposal provides for the secondary use of the **electronic health** data, thus it does not cover samples or data in paper format.
    - As for one Dutch participant, (meta)data about samples can be considered electronic healthdata. Within a single metadata catalogue, the request could lead to different subsequent workflows depending on whether the request concerns electronic data and/or biological samples.
    - In Aragón: approval of requests for samples is handled by the biobank of the Aragonese Health System, not by IACS.
- In France:
    - The data of the National Health Data System (SNDS) can be used. It covers all the health data associated with a health insurance reimbursement, whether collected during a hospital treatment, a doctor's visit, participation in a research cohort or an epidemiological or practice register, etc.
    - There is an exception for genetic data: the access to this data requires obtaining the patient's consent.

- In Finland: genetic & biobank data are under separate jurisdiction, and are not included in the Act for Secondary Use[3] Thus, Findata does not grant permits for such data or samples as of today. However, they can be linked with Findata's data.

Access to health data from a single data holder

- In Finland: Finnish Institute for Health and Welfare (THL) employees can apply for data permits from the institute. If they want to link data from other registers to the THL data they need to go directly to the data holders to get data permits. This falls under the THL legislation.
- In Aragón: as part of its mission, IACS collects data from all data holders in the Aragon region. Then it is compiled in BIGAN. However, when a specific dataset is not yet collected by IACS and therefore not yet available in BIGAN, the data user can go directly to the data holder.
- In France, the Health Data Hub is the unique gateways for requesting access, but once access is granted, access can be provided by other actors.

2.2 Best practices and pain points for multi-country data access applications

Participants were asked to identify, via an online tool, current best practices and pain points for multi-country data access applications.

Figure 3: Summary of current best practices and paint points

	Governance	Data discovery	Delays	Information in ENG	Fees	Other
	• HDH single gateway for requesting access, simplified procedures, permanent access for certain institutions	• metadata catalogue in development	• Actual delays for authorizing data application and making data available	• Information and application form only available in FR	• fees policy under discussion, currently data holders can charge fees	• Individual information (restrictive interpretation of the DPA) • Intellectual property • Complex Data linkage
	• BIGAN single gateway in Aragon autonomous region	• basic catalogue	• no formal time limit for processing/authorizing data applications	• Data request form only available in ESP	• tariff structure	• No national node yet
	• No request portal yet (CBS) • the procedure that has to be followed depends on the data holder (CBS)	• The data user can visit CBS data catalogue • Health-RI is developing a metadata catalogue	•	• Information available in ENG	• tariff structure (CBS)	
	•	• metadata catalogue	• Delays for making data available are relatively short (less than 60 days, but it can take longer depending on the data holder	• information available in English	• tariff structure (Findata)	

Current best practices for multi-country data access applications:

- Standardised metadata catalogue;
- Organisation such as ECDC or Eurostat are able to collect highly standardised data sets from the Member States for some specific purposes (ex. surveillance of antimicrobial resistance);

[3] The Act for Secondary Use covers personal data of the National Institute for Hea National Institute for Health and Welfare, Social Insurance Institution of Finland, National Supervisory Authority for Welfare and Health Valvira; Regional State Administrative Agencies, Finnish Institute of Occupational Health, Finnish Medicines Agency Fimea, Public service organisers of social and health care; Statistics Finland, Finnish Centre for Pensions, Population Register Centre (now: Digital and Population Data Services Agency)

- FAIR principles[4] implementation through research project;
- Federated approaches as PHIRI;
- Mutual recognition of regional ethical committees decisions in Spain. This might be a useful example towards common procedures for ethical committees decisions across Europe;
- Bilateral partnerships between research groups potentially involving national data platforms
- In multi-country applications, it is essential to meet the timelines, in order to bring predictability to customers and data users.
- At CBS, it is possible for universities within the EEA or a country with an adequacy decision to gain secure access to pseudonymised data.

Current pain points for multi-country data access applications:

- Differing definitions of the secondary use of data;
- Duplication of work, need to go through multiple processes in different countries;
- Lack of interoperable metadata catalogue, metadata are in various “standards”, metadata are not machine readable;
- Language issues: no standardised English data access forms, health data often are in local language;
- Trust levels of user’s identity;
- Long delays, little visibility on the timelines, sometimes the timelines for getting access is longer than the availability of the funding;
- No possibility of transfer allowing for pooling of data;
- Difficult to know what fees to expect;

2.3 How does the current situation impact cross-border and multi-country projects?

Some efforts have been made to enable multi-country project:

- English documentation (e.g., Findata and BIGAN provide detailed instruction on how to complete a data access application form);
- Remote access to certain SPEs;
- Efforts to improve local/national processes also translate into better cross-border/ multi-country processes

However, such project remains difficult to carry out:

- Not all documentation / processes available in English language;
- Conditions for use are not always appropriate for crossborder/multi-country projects;
- In Finland, the biggest obstacle is the requirement to use an audited SPE. Currently it inhibits all data transfers outside Finland;
- Need to go through uncoordinated national authorisation processes, that each have their strengths and weaknesses. The process has little readability and is very painful for data users. Ultimately, such projects remain the exception;

[4] The FAIR principles aim at making data Findable, Accessible, Interoperable and Reusable.

3 Session 2: Crossborder and multi-country data access applications under the EHDS regulation

3.1 EHDS draft regulation

3.1.1 Overview of the EHDS draft regulation

The European Commission has presented its proposal for a regulation on the European Health Data Space on May 3rd, 2022. The proposed regulation is part of a larger EU regulatory framework on data, including: GDPR, data governance act, data act, IA Act. It covers both the primary and secondary uses of health data and is currently being discussed in the European Parliament and the Council of the EU.

As such, the proposal establishes the first sectoral data space as foreseen in the framework of the European data strategy. The EU will also set up further other sectoral data spaces.

Chapter IV of the proposal covers the secondary use of data, and is divided into 5 sections:

- Section 1: General conditions (categories of data, authorised and prohibited purposes
- Section 2: Governance and mechanisms (distribution of roles and responsibilities: HDAB, data holders, fees, penalties)
- Section 3: Data permit (data access application, data permit, access for EU/public sector bodies, access to data of a single data holder, secure processing environments),
- Section 4: Cross border access (HealthData@EU infrastructure)
- Section 5: Data quality and utility (dataset description, data quality and utility label, EU datasets catalogue)

As far as the secondary use of health data is concerned, the proposed regulation aims to:

- provide a governance framework for the access and use of health data including common rules and processes around accessing health data, the definition of roles and responsibilities of actors involved (data user, data holder, health data access body)
- allow for cross-border projects through a dedicated infrastructure, HealthData@EU
- promote interoperability and quality of health data.

The TEHDAS Joint Action, currently develops European principles for the secondary use of health data. As such, it has developed:

- A literature review to analyse the existing evidence of barriers to data sharing in Europe
- Guidelines for establishing cross-border partnerships for sharing health data for secondary purposes
- Options and considerations to help clarify the health data governance structure in the EHDS.
- Recommendations for Member States to develop legislation on the secondary use of health data

3.1.2 Relevant provisions for data access applications

Art. 36 - Health Data Access Bodies (HDAB)

- Each Member State designates one or more HDAB, responsible for granting and providing access to data (creation, or existing internal services of public sector bodies)
- When a Member State designates several HDABs, it shall designate one HDAB to act as coordinator

Art. 37 - Tasks of Health Data Access Bodies (see Table 1 infra)

Art. 41 - Duties of data holders

- When a permit has been delivered, data holders shall put the electronic health data at the disposal of the HDAB within 2 months from receiving the request from the HDAB
- In exceptional cases, that period may be extended by the HDAB for an additional period of 2 months.

Art. 45 - Data access application

- Any natural or legal person may submit a data access application. The application is submitted to the relevant HDAB of the country.
- The application shall include:
    - a detailed explanation of the intended use of the electronic health data
    - a description of the requested electronic health data, their format and data sources
    - an indication whether electronic health data should be made available in an anonymised format;
    - where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;
    - a description of the safeguards planned to prevent any other use of the electronic health data;
    - a description of the safeguards planned to protect the rights and interests of the data holder and of the natural persons concerned;
    - an estimation of the period during which the electronic health data is needed for processing;
    - a description of the tools and computing resources needed for a secure environment.
- For access to data from more than one Member State:
    - the data user submits of a single data access application to one of the concerned HDAB (of his choice)
    - The HDAB that has received the application is responsible for sharing the request with the other relevant HDABs
- The Commission may, by means of implementing acts, set out the templates for the data access application

Art. 46 - Data permit

- The HDAB decides to issue or refuse a data permit within 2 months. By way of derogation, the HDAB may extend the period by 2 additional months.
- When the HDAB fails to provide a decision within the time limit, the data permit shall be issued (tacit authorisation).
- Once a permit is granted, the HDAB immediately requests the data from the data holder(s).

- Once the data is received from the data holder, the HDAB makes the data available to the user maximum 2 months after receiving it within a secure processing environment.
- The permit shall not exceed 5 years (duration can be extended once).
- The Commission may, by means of implementing acts, set out the templates for the data permit.

Art. 48 - Access for public bodies and Union institutions

- Public bodies and Union institutions can request access to data, but a data permit should not be required for them.
- The HDAB shall inform these bodies about the availability of the data within 2 months (it may extend the period by 2 additional months where necessary).
- The HDAB shall make the data available to the data user within 2 months after receiving them from the data holder

Art. 49 - Access to data from a single data holder

- Where an applicant requests access to electronic health data only from a single data holder in a single Member State, that applicant may file a data access application or a data request directly to the data holder, complying with the requirements of Art. 45. The single data holder decides on the application to grant or refuse a permit in accordance with Art. 46.
- Multi-country requests and requests requiring a combination of datasets from several data holders shall be addressed to health data access bodies.
- The data holder shall provide access to the electronic health data in a secure processing environment complying with Art. 50 and may charge fees in accordance with Art. 42.
- Within 3 months the data holder shall inform the relevant HDAB of all data access applications filed and all the data permits issued.

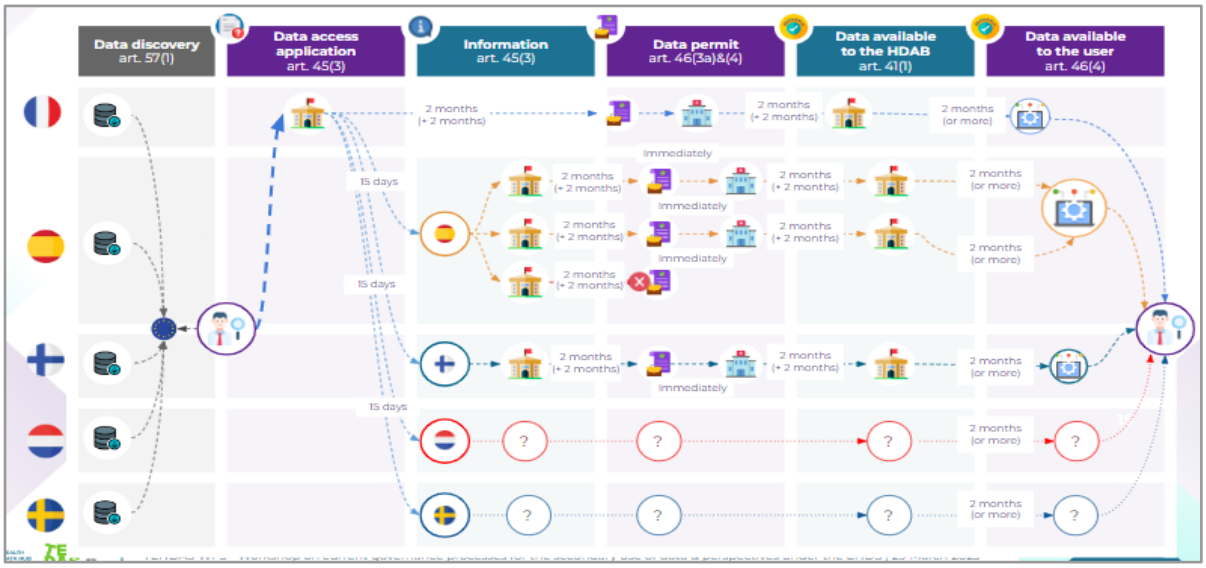
The workshop did not cover data requests pursuant to Art. 47.

3.2 Foreseen processes for a multi-country data access application

Scenario: a researcher requests access to data from France, Spain, Finland, the Netherlands, and Sweden. The working hypothesis is that France and Finland have a unique HDAB whereas Spain (a decentralised state, with 17 Autonomous Communities) has several HDABs.

This working assumption is without prejudice of the future organisation that will be decided at each Member State level.

Figure 4: Foreseen process for a multi-country data access application



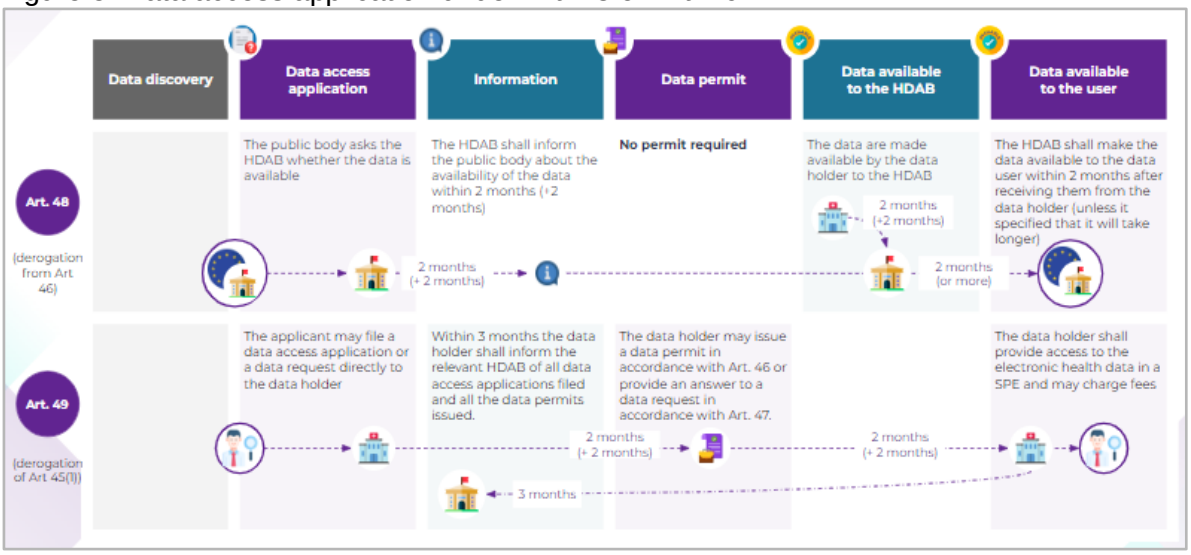
Step	Process
Discovery	The European commission will establish a EU dataset catalogue, connecting the national dataset catalogues established by the HDABs. The data user can visit EU Datasets Catalogue to discover the data available in each country and that way to decide which data to request access for.
Data access application	The data user submits a single common data access application to one of the concerned HDABs (for instance, data application submitted to Findata)
Information	The HDAB receiving the data application request notifies all the national contact points of the Member States mentioned in the application in the data access application (for instance, the national contact points for France, Spain, the Netherlands and Sweden), within 15 days. In the case of a Member State having designated several HDABs, the national contact point transmits the application to all the relevant HDABs in the Member State (for instance, the national contact point for Spain would transmit the application to all relevant HDABs).
Data permit	Each HDABs is responsible for taking decisions to grant or refuse a data permit within their remit, within 2 months of receiving the application (renewable once). For instance, if the application includes Spain, each Spanish HDAB will decide for the data falling in its remit, with the Coordinator responsible for coordinating the requests. Once the permit would be granted, each HDAB would request the

	data to the data holder immediately. NB: The proposed regulation also introduces the notion of 'mutual recognition' where an HDAB could decide to recognise the decision of another HDAB.
Data made available to the HDAB	Each data holder concerned by a data permit is required to provide the health data to the HDAB within 2 months from receiving the request from the HDAB (renewable once.)
Data made available to the user	Finally, each HDAB should make the health data available to the data user within 2 months after receiving them from the data holders (or longer, if specified by the HDAB) in a secure process environment.

NB: This process to request access is the legally required process. Prospective users can exchange with data holders to help them understand the data and collaborations are frequent.

3.3 Derogations to the standard procedure

Figure 5: Data access application under Art. 48 or Art. 49



3.3.1 Application under art. 48 - Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit

Step	Process
Data request	No specific indications are given, this would require further elucidation.

Information	The HDAB would inform the body requesting the data about the availability of the data within 2 months (it may extend the period by 2 additional months where necessary)
Data permit	**A data permit is not required** The HDAB(s) request(s) the data from the data holder immediately.
Data made available to the HDAB	Each data holder concerned by the request is required to provide the health data to the HDAB within 2 months from receiving the request from the HDAB (renewable once.)
Data made available to the user	The HDAB makes the data available to the data user within 2 months after receiving them from the data holder (or longer if specified by the HDAB) within a secure processing environment.

3.3.2 Application under art. 49 - Access to electronic health data from a single data holder

Step	Process
Data access application	The data user who would like to request access to health data from a single data holder in a single Member State, files a data access application or a data request directly to the data holder. NB: Multi-country requests and requests requiring a combination of datasets from several data holders need to be addressed to health data access bodies.
Data permit	The data holder would issue a data permit in accordance with Art. 46, i.e., within 2 months of receiving the application (renewable once).
Information	Within 3 months the data holder would inform the relevant HDAB of all data access applications filed and all the data permits issued.
Data made available to the user	The data holder shall provide access to the electronic health data in a secure processing environment

3.4 Discuss our understanding of the EHDS regulation

Secure Processing Environnement (SPE)

- Participants discussed whether SPEs could be provided by other parties (private or public) than the HDAB. It was mentioned in that case that common requirements/standards for such SPEs would be required.
- As pointed out by representatives of the European Commission, nothing in the EHDS proposal prevents data to be transferred to other country's SPE (or made available in an European Commission SPE).
- Participants discussed whether the following situation would already constitute a transfer of data: a user from Member State B accessing data from Member State A in the SPE of Member State A. For most participants, if access to data is provided through a SPE, the health data never leaves the country.
- It was highlighted that additional clarity on the possibility and conditions of pooling data from several countries in one SPE and on remaining policy barriers around such transfers.

HDABs

- A participant noted that HDABs as foreseen in the EHDS proposal could be very "different creatures" which could lead to inconsistencies and complications for the secondary use of health data. It has been suggested that it could be interesting to define criteria or guidelines for setting up HDABs, and especially for the Coordinator.
- Ideally, HDABs would have good knowledge on the system put in place in other countries. This might be of relevance for supporting public sector bodies/Union institutions seeking access to data from another country under Art. 48 but also other data users.

Standardised processes

- Participants agreed that all data application procedures must be highly standardised. For instance, single data holders should always be under the supervision of HDAB when assessing applications and providing access to data under Art. 49.

Joint controllership

- A participant pointed out that there are challenges when defining the joint controllership, in multinational studies, or even at the country level, and asked whether all HDAB would be, together, joint controllers for all data delivery, even for data requests made under Art. 49. Another participant pointed out that in France currently the HDH is controller of the provision of data within a SPE, but the user is controller of the data processing according to the permit, so that in practice there are separate controllerships for the different actors in the process, which could be more acceptable than joint controllership
- As explained by the European Commission, GDPR and the case law of the European Union Court of Justice would apply.

Other

- A participant highlighted that a translation of applications might be required for cross-border and multi-country requests to effectively allow applications and review in different countries.
- Participants agreed that the concept of mutual recognition would need to be further refined in order to be used in practice.

3.5 Roles and responsibilities for tasks under Art. 37 (data holder, HDAB, coordinator)

Participants discussed several use cases (Figure 6) to verify that all stakeholders have a shared understanding of how cross-border and multi-country applications would work under the proposed EHDS regulation. This allowed in particular to discuss what role data holders, HDABs and the coordinator of HDABs should have with regards to the tasks listed under Art. 37. This was also the opportunity to identify other aspects that may still require further clarification. The results are presented in Table 1.

Figure 6: Use cases

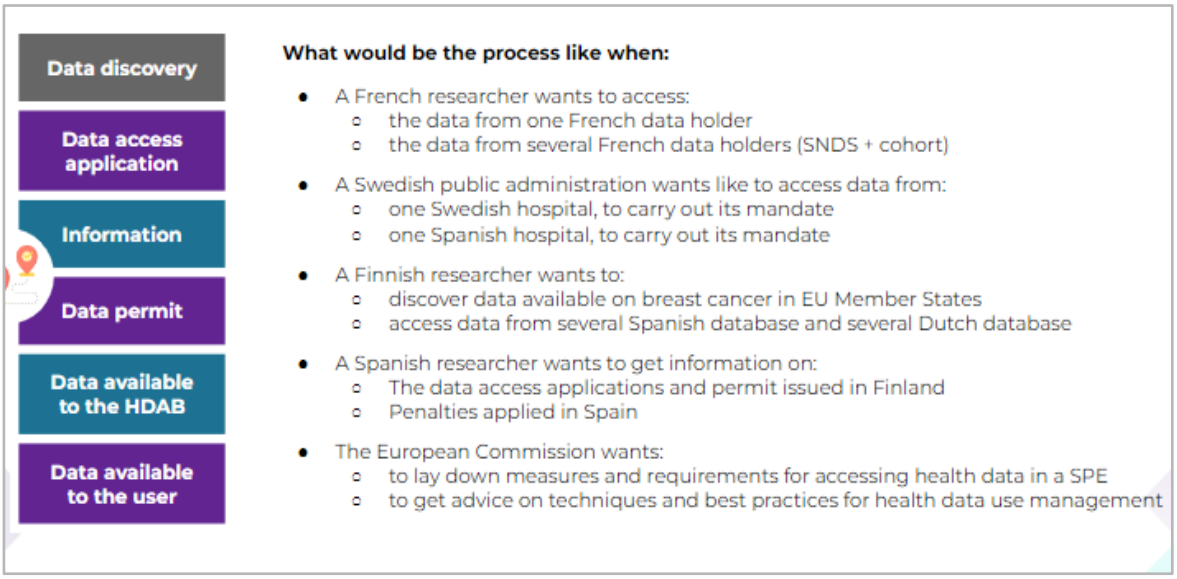


Table 1: Roles and responsibilities for tasks under Art. 37 (data holder, HDAB, coordinator)

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
(a) decide on data access applications	The regulation specifically states that the Coordinator should coordinate requests with concerned HDABs	Coordinating	Responsible	Responsible (only under art. 49, request to a single data holder)
(b) support public sector bodies in carrying out the tasks enshrined in their mandate	This could be linked to art. 48 (example: a public health institute pursuing public health surveillance) This task could be given to the coordinator or	Coordinating or Responsible *NB: not covered in the regulation so far*	Contributing or Responsible	/

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
	coordinated by the coordinator.			
(c) support Union bodies in carrying out tasks enshrined in their mandate	This could be linked to art. 48 (example: a Union agency pursuing post-authorisation studies) This task could be given to the coordinator or coordinated by the coordinator.	Coordinating or Responsible *NB: not covered in the regulation so far*	Contributing or Responsible	/
(d) process health data for the purposes set out in Article 34 (collection, combination, preparation and disclosure of those data)	Example: request for data related to several HDABs in one country, is there a role for the HDAB coordinator to make that available if permits are granted? EC comment: When it comes to the organisation at the national level, there is no prescription against the fact that the coordinator would combine all the data. This is up to each Member State.	Centralises for HDABs (especially linkage) *NB: not covered in the regulation so far, would be good to pilot this*	Responsible	Responsible (not for linkage)
(e) process health data from other relevant data holders	E.g. to process data for a data request (in the meaning of Art. 47 EHDS draft regulation)	Aggregates/centralises *NB: not covered in the regulation so far, would be good to pilot this*	Responsible	/
(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets	There is definitely a need for some level of harmonisation, and an implementing act is foreseen on this matter. Ideally the HDABs should not become too vulnerable	Harmonises practices of HDABs *NB: The draft regulation also foresees an implementing*	Responsible	Responsible *NB: Data holders should also be able to*

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
	for litigation; a solution where the holders and users are responsible/accountable for making sure IP/trade secrets are protected/ not misused may be preferable	*act to make it more precise*		*include relevant information in the metadata records*
(g) gather and compile or provide access to the health data from the various data holders and put those data at the disposal of data users in a SPE	/	Centralises (if pooling of data from >1 HDAB is required) *NB: not covered in the regulation so far, would be good to pilot this*	Responsible	/
(h) contribute to data altruism activities	**/**	Harmonises practices among HDABs *NB: not covered in the regulation so far*	Responsible	/
(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines	**/**	Harmonises practices among HDABs *NB: not covered in the regulation so far,*	Responsible	/
(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation	**/**	Harmonises practices among HDABs *NB: not covered in the regulation so far*	Responsible	/

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
of the data quality and utility label				
(k) maintain a management system to record and process data access applications, data requests and the data permits issued	E.g for necessary reporting under Art. 39 and also to be able to provide a tool for the data users to access their requests and status of these a centralisation of this information appears necessary at Member State level	Centralises *NB: not covered in the regulation so far, would be good to pilot this*	Responsible	Responsible for informing HDAB
(l) maintain a public information system to comply with the obligations laid down in Article 38;	Necessary for transparency purposes to have a single portal where a citizen can have the information on all the applications and projects.	Centralises *NB: not covered in the regulation so far, would be good to pilot this*	Responsible	Responsible for informing HDAB
(m) cooperate at Union/national level to lay down appropriate measures and requirements for accessing health data in a SPE	If we have several HDABs per country, one actor needs to represent them at national/European level in specific discussion/decision-making fora. The European Commission may provide a SPE	Represents HDABs at national/European level *NB: The draft regulation also foresees an implementing act to make it more precise*	Responsible	
(n) cooperate at Union/national level and provide advice to the Commission on techniques and best practices for health data use and management	If we have several HDABs per country, one actor needs to represent them at national/European level in specific discussion/decision-making fora.	Represents HDABs at national/European level *NB: The draft regulation foresees an EHDS Board to align on high-level questions and the joint*	Responsible	

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
		controllership group for operational decision-making. The role of the Coordinator in these groups may need to be clarified.		
(o) facilitate cross-border access to health data for secondary use	The regulation specifically states that the National contact point is responsible, ideally that would be the same as the Coordinator.	Responsible *NB: In the draft regulation, it is said that the national contact point can be the Coordinator.*	/	/
(p) send to the data holder a copy of the corrected, annotated or enriched dataset	If there are several HDABs, it would make sense to harmonise practices so that data users and data holders know what to expect no matter which HDAB they interact with.	Harmonises practices among HDABs *NB: not covered in the regulation so far*	Responsible	
(q) make public, through electronic means:				
(i) a national dataset catalogue	This appears to need to be done by the national contact point connected to HealthData@EU.	Responsible *NB: In the draft regulation, not completely clear if this is an attribution of the national contact point.*	/	/
(ii) all data permits, requests and applications	A national tool seems to be required for this, compiling inputs from all national HDABs	Centralise *NB: not covered in the regulation so far*	Responsible	Responsible

Tasks	Comments/discussions	Distribution of tasks		
		Coordinator (in case of >1 HDAB)	HDABs	Data holder
on their websites				
(iii) penalties applied pursuant to Article 43;	A national tool seems to be required for this, compiling inputs from all national HDABs	Centralise *NB: not covered in the regulation so far*	Responsible	
(iv) results communicated by data users pursuant to Article 46(11);	A national tool seems to be required for this, compiling inputs from all national HDABs	Centralise *NB: not covered in the regulation so far*	Responsible	Responsible
(r) fulfil obligations towards natural persons pursuant to Article 38;	In order to ensure rights of natural persons, harmonised practices at EU (and at least national) level are required. A national tool would also make it easier for natural persons.	Harmonises *NB: not covered in the regulation so far, could be good to have a national tool for this*	Responsible	Responsible
(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;	In order not to confuse data users and data holders, it seems important to harmonise practices among HDABs.	Harmonises *NB: not covered in the regulation so far*	Responsible	Responsible (?)
(t) fulfil any other tasks related to making available the secondary use of electronic health data in the context of this Regulation.	Relatively vague task, it appears useful to have coordination among HDABs if several HDABs exist in a country.	Harmonises *NB: not covered in the regulation so far*	Responsible	/

4 Perspectives and recommendations

During and after the workshop, the participants highlighted that the EHDS regulation would bring improvements with regards to the possibility to conduct cross-border or multi-country projects. Yet, it does not sufficiently cover or clarify all topics, and a number of issues remain open, requiring further careful examination and consideration.

4.1 Improvements brought about by the EHDS regulation

For many, the EHDS will allow for "more and better medical statistical research". One participant recognised the substantial demand from the ecosystem (especially from the research community) and that the EHDS could bring momentum to set the basis of real-world data sharing.

Participants also agreed that the EHDS legislation provides for:

- An ambitious perimeter of categories of data for secondary use of health data.
- Coherent, readable and efficient governance, in particular with regards to the roles of data user, data holder, and HDAB.
- Ambitious deadlines for authorising and making data available.
- A pragmatic implementation of the GDPR with collective information being the rule (instead of individual information).
- The possibility to file a data access application directly to a single data holder (art. 49).
- Clarification on data access application & data permit processes in the context of cross-border or multi-country projects with notably:
    - An EU Datasets catalogue connecting the national catalogues of datasets established by the HDABs allowing the discovery of data available across countries;
    - Allowing the data user to submit a single data access application to one of the concerned HDABs;
    - A potentially reduced divergence of health-sector specific GDPR implementation facilitating the cross-border re-use;
    - An increased readability of the overall rules through somewhat harmonised frameworks on fees, sanctions and secure processing environments.

4.2 Pending issues

As a general remark, one participant noted that building the EHDS will bring costs to Member States and other stakeholders and that additional EU funding may be required to achieve the overall ambition.

Governance and distribution of tasks in the health data access governance

As far as the governance and distribution of tasks is concerned, 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, and of the national contact point despite the long list of tasks for HDABs in Art. 37;
- The possibility for Member States to adopt simplified procedures;

- The application of art. 48: does art. 48 allow public bodies of country A to access data of country B without a permit?

SPE

Participants pointed out the need to clarify the use of a SPE. The need for common requirements/standards for SPEs was mentioned as well as the question of the possibility and mechanism to pool data in a single SPE when required.

Adapt rules of GDPR to the secondary use of health data

Generally speaking, and unless specified otherwise within the proposed regulation, GDPR rules apply to the EHDS. This could reduce some of the fragmentation of GDPR implementation between Member States, but a few questions remain open:

- The operationalisation of the requirement to inform natural persons about “clinically significant findings”.
- The situations in which privacy impact assessments are required could be further specified (PIA).

Interoperability

The regulation provides no obligations and little guidelines with regards to interoperability standards to be adopted. 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.

Other

Finally, one participant asked how to meet company IP-rights and trade secrets in all steps and ensure that companies have first-hand rights to their own data.

4.3 Recommendations for a successful implementation of the EHDS for the secondary use of data regulation

Guidelines for setting up HDABs

- 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. Also, other actors (e.g. patient associations) would benefit from having a single actor to turn to 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.
- 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. In Art. 49, the proposed regulation already provides for the possibility for a data holder to make available the data it holds. This also seems to apply in situations where an actor such a grouping of healthcare facilities is federated (e.g. a grouping of healthcare facilities). It therefore 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 Art. 37.

- 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.

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 coordinator can also represent all HDABs at the national/European level, centralise certain inputs/outputs of other HDABs, harmonise the operations of HDABs etc. 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 Art. 37.
- 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.

Mutual recognition

- The 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.

Clarify use of SPEs

- As highlighted above, a clear vision of how SPEs 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 and which for now is explicitly excluded in some countries. Also, more clarity on how the requirements of Art. 50 will be articulated with pre-existing national technical and security requirements for the hosting and manipulation of pseudonymised health data is required

Interoperability of health data

- Include rules (or at least guidelines) around standards for semantic interoperability of health data to be used within the EHDS. The standards used within the primary use (Art. 5 and 6) for collection of priority categories of health data will already have a beneficial impact on secondary use.

Funding

- While some countries have made investments in the secondary use of health data and the EU has also supported some investments in that regard, additional funding on this topic 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.

- If fees are to support the setup of the EHDS, the regulation should adopt a full cost logic and also include costs related to the preparation, combination or pseudonymisation of health data in the fees that HDABs can charge, and costs related to the collection of data for the data holders.

5 Glossary

Aineistokatalogi: THL metadata catalogue

BIGAN (*Big Data Sanitario de Aragón*): Biocomputing Unit at the Institute for Health Sciences in Aragon

CBS (*Centraal Bureau voor de Statistiek*): Statistics Netherlands

CEICA (*Comité de Ética de la Investigación de la Comunidad de Aragón*): Ethics Committee of Clinical Research of Aragon

CESREES (*Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé*)*:* independent French ethical and scientific committee

CNIL: Commission on Information Technology and Liberties

DPA: Data protection authority

EHDS: European health data space

Findata (*Sosiaali- ja terveysalan tietolupaviranomainen Findata*): Finnish Social and Health Data Permit Authority Findata

GDPR: General Data Protection Regulation

HDAB: Health data access body

HDH: French Health Data Hub

IACS *(Instituto Aragonés de Ciencias de la Salud)*: Health Sciences Institute in Aragon

Kela: Finnish Social Insurance Institution

PIA: Privacy impact assessment

RIVM (*Rijksinstituut voor Volksgezondheid en Milieu*): Dutch Institute for Public Health and the Environment

SEHA: Swedish eHealth Agency

SPE: Secure processing environment

THL: Finnish Institute for Health and Welfare