M6.2 - Draft guideline for data users on good application and access practice

TEHDAS2 – Second Joint Action Towards the European Health Data Space

19 January 2025

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0 Document info

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0.1 Authors

Lead Author(s)	Lead organisation
Zdenka Dudová	Masaryk University, Czechia
Pinar Alper	Luxembourg National Data Service (LNDS), Luxembourg
Gergo Csarnai	Luxembourg National Data Service (LNDS), Luxembourg
Beatriz Barros	Serviços Partilhados do Ministério da Saúde (SPMS), Portugal
Sara Marques	Serviços Partilhados do Ministério da Saúde (SPMS), Portugal
Other Authors	**Organisation**
Gunter Maier	Austrian National Public Health Institute (GÖG), Austria
Irene Schluender	TMF e.V., Germany
Réka Kovács	ESZFK eHealth Service and Development Center, Hungary
Christina Hilmarsen	Norwegian Institute of Public health (NIPH), Norway
Marius Ciutan	National Institute of Health Services Management, Romania
Daniela Georgeta Popovici	National Institute of Health Services Management, Romania
Pavol Rieger	National Health Information Centre, Slovakia

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Contents

1 Executive summary

The European Health Data Space (EHDS) Regulation aims to harmonise and facilitate the cross-border secondary use of electronic health data. A key component is the standardised data access and request form, ensuring a common application procedure. Guidelines are developed to inform decision-making and standardise practices across Member States, ensuring consistent, secure handling of health data in compliance with EU regulations.

This guideline, based on the EHDS2 pilot project and its preliminary implementation in Release 2 of the EU Central Platform, provides practical, step-by-step instructions for applicants. It covers:

- selecting the appropriate application pathway (data access vs data request);
- preparing necessary documents and information;
- meeting obligations under the EHDS Regulation;
- understanding timelines, expectations and the role of health data access bodies (HDABs) during the application process.

By following this guideline, applicants will:

- increase their chances of successful application by providing thorough, accurate information;
- facilitate faster and more efficient reviews by HDABs, reducing the time to obtain the data permit;
- ensure compliance with applicable regulations, including the EHDS Regulation and the General Data Protection Regulation (GDPR).

2 List of abbreviations

Abbreviation	Description
Art	Article
CPU	Central Processing Unit
DPO	Data Protection Officer
EDI	Electronic Data Interchange
EDPB	European Data Protection Board
EEA	European Economic Area
EHD	Electronic Health Data
EHDS	European Health Data Space
EU	European Union
GDPR	General Data Protection Regulation
GPU	Graphics Processing Unit
HDAB	Health Data Access Body
IBAN	International Bank Account Number
IDE	Integrated Development Environment
OECD	The Organisation for Economic Cooperation and Development
Peppol	Pan-European Public Procurement OnLine
RAM	Random Access Memory
SPE	Secure Processing Environment
VAT	Value Added Tax
VPN	Virtual Private Network
WHO	World Health Organisation

3 Introduction

Advancing health data use in the European Health Union

As part of the European Health Union, the European Union (EU) is advancing the use of health data for secondary purposes, including research, innovation and policymaking. Smooth and secure access to data will drive the development of new treatments and medicines and optimise resource utilisation—all with the overarching goal of improving the health of citizens across Europe.

TEHDAS2, the second joint action Towards the European Health Data Space, represents a significant step forward in this vision. The project will develop guidelines and technical specifications to facilitate smooth cross-border use of health data, and support data holders, data users and the new health data access bodies in fulfilling their responsibilities and obligations outlined in the European Health Data Space (EHDS) Regulation.

TEHDAS2 focuses on several critical aspects of health data use.

- Data discovery: findability and availability of health data, ensuring it is accessible for secondary purposes.
- Data access: developing harmonised access procedures and establishing standardised approaches for granting data access across Member States.
- Secure processing environment: defining technical specifications for environments where sensitive health data can be processed safely.
- Citizen-centric obligations: providing guidance on fulfilling obligations to citizens, such as communicating significant research findings that impact their health, informing them about research outcomes and ensuring transparency in how their data is used.
- Collaboration models: developing guidance on collaboration and guidelines on fees and penalties as well as third country and international access to data.

TEHDAS2 will contribute to harmonised implementation of the EHDS Regulation through the concrete guidelines and technical specifications. Some of these documents and resources will also provide input to implementing acts of the regulation. Hence, the joint action will increase the preparedness for the EHDS implementation and lead to better coordination of Member States' joint efforts towards the secondary use of health data, while also reducing fragmentation in policies and practices related to secondary use.

3.1 Target audience

The target audience of this Guideline are health data applicants ("Applicant" or "Applicants") and health data users.

3.2 Purpose

The purpose of this guideline document is as follows.

- Provide essential information and guidance for completing:

  - a well-founded “data access application” to access individual-level electronic health data for secondary use in an anonymised or a pseudonymised format;
  - a well-founded “data request” for an answer to health data in an anonymised, aggregated (non-individual-level) statistical format;
  - and thereby support applicants in becoming health data users.
- Inform the applicants on the process to gain access to electronic health data for secondary use purposes, with that, enable applicants to make informed decisions before submitting a data access application or a data request.
- Educate and raise awareness about applicants’ and health data users’ (from EU and EEA countries) rights and obligations throughout their journey from after the data discovery to receiving the permit for the health data use or health data statistical anonymised results, as well as using such data (see Appendix 1: User journey eventually).
- Provide the applicant with instructions on how to submit grievances or disputes in case their application is rejected or delayed.

4 Key terminology

Health data access application: An application seeking to access individual-level electronic health data for secondary use in an anonymised or a pseudonymised format.

Health data access body (HDAB): Member state-designated data permit authority that facilitates the secondary use of electronic health data. HDABs decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in Secure Processing Environments. HDABs systematically track the data request and data access applications received and the data permits issued. As per Article 58 of the EHDS, HDABs are required to publicly list information on the data permits issued.

Heath data request: The applicant may submit a health data request for the purposes referred to in **Article 53** of the EHDS Regulation with the aim of obtaining an answer only in anonymised statistical format.

Health data applicant: A natural or legal person submitting a health data access application for the purposes referred to in **Article 53** of the EHDS Regulation to the HDAB.

Health data holder: An entity that processes electronic health data as a data controller for the purposes of provisioning care or healthcare, developing healthcare products, services, wellness applications and undertaking healthcare research, or processing healthcare data for innovation, policy development, official statistics or patient safety or for regulatory purposes.

Health data user: A natural or legal person, including European Union institutions, bodies or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, health data request approval or an access approval by an authorised participant in HealthData@EU etc.

Data permit: An administrative decision issued to a health data user by a health data access body to process certain electronic health data specified in the data permit for specific secondary use purposes based on conditions laid down in Chapter 4 of the EHDS Regulation (Article 2(aa)).

Data minimisation: A principle identified in Article 5 of the GDPR, mandating organisations to only collect, store and process personal data that is absolutely necessary to achieve their specific purpose.

Data controller: Identified by Article 4 of the GDPR as any natural or legal person, public authority, agency or other body that determines the purposes and means of processing personal data. The controller is the party that determines why the processing of personal data takes place and how the processing will take place.

Legal basis of data processing: Identified by Article 6 of the GDPR as the conditions under which personal data processing is considered lawful. And for the purposes included in EHDS, the processing is based on "public interest"

Secure Processing Environment (SPE): Defined in Article 73 of the EHDS as an environment in which access to electronic health data can be provided in following a data permit. An SPE is subject to technical and organisational measures and security and interoperability requirements. Specifically allowing access to only those persons listed in the permit, as well as user authentication, authorisation, restricted data handling, logging and the compliance monitoring of respective security measures.

Transfer of data outside the EU/EEA: Defined in Chapter 5 (Article 44 to 50) of the GDPR as general principles, adequacy decisions, appropriate safeguards and specific derogations for transferring personal data to third countries or international organisations. The European Data Protection Board (EDPB) identifies three cumulative criteria to identify a transfer outside the EEA:

- ”a controller or a processor is subject to the GDPR for the given processing;
- this controller or processor discloses by transmission or otherwise makes personal data available to another organisation (controller or processor);
- this other organisation is in a country outside EEA or is an international organisation.”

Trusted health data holder: Member State designated health data holder for whom a “simplified” procedure can be followed for the issuance of data permits as defined in Article 72 of the EHDS. Trusted health data holders leverage their expertise on the data they hold to assist the HDAB by providing assessments of data requests or access applications. Once data permits are authorised, these trusted data holders provide the data within an SPE that they manage.

5 Scope

This guideline is part of a series developed under TEHDAS2 to operationalise the EHDS Regulation, specifically addressing Chapter IV on secondary use of health data. The scope of this guideline begins after the data discovery phase, once the applicant has identified the datasets of interest in the EU dataset catalogue and is ready to apply for the data via the central platform or any HDAB. See Appendix 1: User journey for better insight into the described phases. The guideline covers the entire process of applying for health data access, including preparing necessary information, submitting the application and negotiating with the HDAB. It concludes with insights into the timeframes for different steps after access is granted and conditions of use after the permit.

It focuses on the data applicant role, providing:

- clear instructions for completing data access applications (for anonymised or pseudonymised individual-level data) and data request (for aggregated anonymised results);
- detailed guidance on preparing required information;
- an overview of applicant obligations and timelines.

All applicants and data requesters are strongly encouraged to familiarise themselves with the entire application process by thoroughly reviewing this guideline before initiating their access application or request. This comprehensive document aims to clarify and simplify the process of applying for or requesting health data through HealthData@EU.

6 Before starting the health data access application or a health data request

This chapter provides key information for health data applicants before initiating a data access request via the EU dataset catalogue. Once the applicant has identified the datasets of interest and collected them in the “dataset basket”, they are ready to begin the application process. At this stage, the applicant must select the appropriate application path based on their needs. Under the EHDS Regulation, the use of health data for secondary purposes is explicitly defined and the process distinguishes between two application types. Taking into account the specific purposes of the processing, personal electronic health data should be pseudonymised or anonymised as early as possible in the process of making data available for secondary use.

Health data access application for access to anonymised or pseudonymised individual-level electronic health data within a secure processing environment.

- Example of research question requiring anonymised or pseudonymised individual-level electronic health data: What are the long-term health outcomes of patients with Type 2 diabetes who have undergone bariatric surgery compared to those who have not, considering individual patient characteristics such as age, gender and comorbidities?

- Reason: This research requires detailed, patient-level data to analyse individual health outcomes and identify patterns or correlations based on specific patient characteristics.

Health data request for access to anonymised, aggregated (non-individual-level) statistical results.

- Example of research question requiring anonymised, aggregated (non-individual-level) statistical results: What is the average incidence rate of Type 2 diabetes in the population over the past decade and how has it changed annually?
- Reason: This research focuses on overall trends and incidence rates in the population, which can be addressed using aggregated statistical data without the need for individual-level information.

Before proceeding, it is essential to assess your need and understand the documentation and justifications required for each path (see What documents and information to prepare in advance to the application filling in chapter 3.5) and ensure compliance with applicable laws and principles such as data minimisation.

This guideline relates primarily to the health data access application procedure. The simplified data request procedure is mentioned where it appears necessary.

6.1 Which application path?

HDABs prioritise the protection of individual-level data by granting access to anonymised statistical data wherever possible. Anonymised individual-level data are the default option and HDABs will only make pseudonymised individual-level data available if it is essential for the intended purpose **(Article 53**). Applicants will need to provide a clear argument if pseudonymised data are required (**Article 68(c)**). Selecting an incorrect path to achieve the given objectives may result in delays or additional scrutiny.

Based on the information provided in a data access application or data request the HDAB will either grant or reject the application or request and determine the specific restrictions on the data usage, e.g. dissemination level.

If a data access application is rejected, a detailed explanation of the reasons will be provided (**Article 57**). The decision can be appealed and a structured process for resolving disputes between stakeholders is available. Transparency and fairness throughout this process are ensured by the EHDS Regulation.

6.1.1 Health data request

Applicants should choose this path if anonymised, aggregated data or statistical results meet their objectives. This path is ideal for analyses where detailed individual-level data are not required (e.g. to assess population-level trends or summary statistics) or for querying datasets to obtain further anonymised aggregated details on its contents (e.g. how many individuals with mutation X are present in dataset D) and there is no need for the data user to access the datasets themselves (**Article 69**).

Key features include:

- applicants receive anonymised, aggregated outputs generated by the HDAB or trusted health data holder;
- no pseudonymised or anonymised individual-level data are shared with the applicant;
- the HDAB retains full control over the individual-level data used to produce these results;
- this pathway is suitable when aggregated statistical data are sufficient to meet the applicant's objectives.

Examples

- If a policymaker needs high-level aggregated statistics, such as the number of cancer diagnoses in a region, they would submit a data request. This approach provides summary statistics and avoids accessing detailed individual-level data.
- For a researcher aiming to determine the prevalence of diabetes and hypertension in a specific age group across Member States, a data request can provide anonymised counts of individuals meeting these criteria. This would help the researcher assess whether a more detailed data access application is necessary.

Tip: In some cases it might be easier for the researcher to ask further details to the HDAB about the specifics of the dataset of interest. They can contact HDAB before making the application in order to obtain such info.

6.1.2 Data access application

Applicants should select this path only when individual-level personal data are necessary to achieve the objectives and aggregated statistical results are insufficient to meet the needs. Users can work with the data in a Secure Processing Environment (SPE) when granted the access. This path can apply to two types of datasets under the conditions stipulated in the EHDS Regulation.

1. Anonymised datasets: when direct access to anonymised datasets is necessary for the intended analysis.
2. Pseudonymised datasets: when anonymised data are insufficient to achieve the objective of the processing and a clear justification is provided.

Applicants must explain why the data applied for (anonymised or pseudonymised) are necessary for their purpose and demonstrate compliance with data minimisation principles. The HDAB evaluates applications for both compliance and necessity. All electronic health data can be accessed only within an SPE, ensuring strict data protection and preventing unauthorised re-identification.

Example: If a researcher needs to study the long-term impact of diabetes treatments across multiple Member States, they may require pseudonymised data to link patient records from national registries. Aggregated data would not suffice, as the researcher needs to track individual treatment outcomes over time. The application must justify why pseudonymised data is essential and confirm adherence to GDPR and EHDS requirements, including data minimisation.

6.2 Who can apply?

Under the EHDS Regulation, any natural or legal person may apply for access to health data for secondary use for lawful purposes (**Article 67(1)**). This only apply for EEA's persons and those established in a third country that is recognised as providing reciprocal access to EU-based data applicants to data held by holders in that third countries via an implementing act pursuant to Article 90(2), or where they are established in a third country that has become an authorised participant in HealthData@EU pursuant to **Article 75(5)**. However, please note that this possibility for designation will only apply after a long transitional period of 10 years from the entry into force. The right to apply does not guarantee that access will be granted.

Example categories of potential data applicants:

- public authorities
- healthcare providers
- researchers and research institutions
- private entities and companies
- developers of AI systems for healthcare
- educational institutions
- national health care authorities
- natural persons.

6.3 Allowed purposes for secondary use of health data

Access to data categories specified in **Article 51** for secondary use should benefit society, such as through research and development of new medicines, medical devices and healthcare products and services at fair prices for Union citizens (**Article 53**). It should also enhance access to these products and services across all Member States.

Lawful purposes for processing electronic health data for secondary use under the EHDS Regulation (**Article 53**) include the below.

a. **Public health – protect against health threats and ensure quality and safety of healthcare.**
   - Choose this purpose if:
     - you aim to monitor, prevent or respond to health threats, such as infectious disease outbreaks or environmental health hazards;
     - you need to study trends in vaccination uptake, disease prevalence or health outcomes for specific populations.
   - Example: Monitoring vaccination coverage to identify areas with low uptake and implementing targeted campaigns to boost vaccination rates.

b. **Support public bodies – help government and EU health institutions.**
   - Choose this purpose if:
     - your work supports policymaking, resource allocation or other administrative functions of public health institutions;

  - you plan to assist government bodies in designing evidence-based healthcare policies or initiatives.
- Example: Analysing hospital admission trends to help a health ministry allocate resources during a health crisis.

c. Statistics – create health-related statistics.

- Choose this purpose if:
  - you aim to generate anonymised health statistics for use in reports, dashboards or publications;
  - you are producing summary-level insights, such as disease prevalence or health service usage rates.
- Example: Producing annual statistics on chronic disease prevalence across Member States, segmented by demographic factors.

d. Education – for teaching in health and care.

- Choose this purpose if:
  - you plan to develop educational materials or training for healthcare professionals or students;
  - you want to create anonymised case studies for use in academic or professional healthcare programs.
- Example: Developing simulated case scenarios for training medical students in diagnosing rare diseases.

e. Research – for health-related scientific studies.

- Innovation – develop new health products and services.
  - Choose this purpose if:
    - you are conducting research to create new medical devices, therapies or healthcare technologies.
  - Example: Using pseudonymised data to study genetic markers for rare cancers and develop precision medicine approaches.
- Algorithm testing – train and test medical algorithms.
  - Choose this purpose if:
    - you aim to train, validate or refine machine learning models or other algorithms in healthcare.
  - Example: Training an algorithm to detect early signs of heart disease using anonymised health records.

f. Personalised healthcare – provide tailored healthcare based on others' data.

- Choose this purpose if:
  - you are studying ways to personalise treatments or healthcare interventions based on patient-specific factors, such as genetics or comorbidities.
- Example: Analysing pseudonymised health records to identify optimal treatment plans for patients with specific genetic profiles.

6.4 Prohibited purposes for use of health data

Under the EHDS Regulation any use of health data that falls outside approved purposes is prohibited, especially if it negatively affects upon individuals or groups. See below the purposes prohibited according to **Article 54**.

a. Detrimental decisions – decisions that negatively impact individuals based on their health data.
b. Insurance discrimination – decisions to exclude or alter insurance benefits or premiums based on health data.
c. Advertising – advertising or marketing to health professionals, organisations or individuals using health data.
d. Unauthorised access – sharing health data with third parties not specified in the data permit.
e. Harmful products – development of products or services that could harm individuals or society, such as illicit drugs or items against public order or morality.

Detailed guidance on completing the "Purpose" section of the application form is provided later in this document, see Section 5 – Purpose of planned data use. Applicants are encouraged to refer to that section for step-by-step instructions and examples.

6.4.1 What documents and information to prepare before filling in the application

Standardised electronic forms are provided for processing data access applications and data requests. These forms ask for various formal criteria, which applicants can usually prepare for. To ensure that the application process runs as quickly and smoothly as possible, it is advisable to follow the below checklist to have the information and documents ready before starting the application process. The respective fields of the application form are described in detail in the section Data access application form.

- ❑ Project description for public announcement
  - A summary of the project that can be shared with the public by the HDAB on their website within 30 working days after issuance of the data permit or reply to a data request. Should not include any confidential information (**Article 58**).
- ❑ Summary of the project plan for decision making purposes
  - Maximum two pages long, written in one of the official EU languages.
  - This document will not be made public and thus can include also confidential information.
  - Payment details (Section 4 of the application form) for the person and organisation that will receive the bills related to this application. Include whether they can receive e-invoices, as well as the project number and cost account.
- ❑ Detailed data description that the applicant needs for the project/study
  - Include specifics of the datasets needed for the project or study.
- ❑ Approvals depending on the source of the data
  - Some countries need ethical review documents which need to be attached (Section 6 of the application form).
- ❑ In a case of combining existing data in applicant's possession with the dataset of interest (**Article 57**), the applicant shall have prepared the following to be

provided in the application form to the HDAB (For applicants with existing datasets, Section 7 of the application form):

- Prior consent or permit to existing datasets that the applicant already has from the HealthData@EU infrastructure or outside the infrastructure.
    - Consent is required as a legal basis if the data which are supposed to be combined with the datasets of interest were initially collected based on consent.
    - If the data in the applicant's possession were collected under a prior permit (outside the HealthData@EU), they must provide documentation of that permit, including details such as the issuer, date, validity period and any identifying information (e.g. permit code).

❑ Prepare the SPE machine specifications depending on the complexity and volume of operations (Section 8 of the application form). Applicants will be asked to specify:

- The memory needed for their analysis (RAM).
- The number and type of processors required (Processing Units [CPU/GPU]).
- Adequate space for both data and software.
- Operating system compatible with their software and tools.

❑ **Review Article 68** Data permit for the complete list of criteria that must be met to obtain a data permit. Applicants should ensure that their application meets all criteria listed in Article 68.

7 How to apply for dataset(s) of interest

In the data access (permit) application phase, the health data applicant applies for access to the individual-level health data or requests aggregated, statistical data. To do so, data users should provide all the necessary information to the relevant HDABs.

7.1 National datasets from one Member State

For datasets located in a single Member State, applications must be submitted to the national HDAB in that Member State. If multiple HDABs exist within a country, the applicant should apply at the HDAB which is the most relevant for the dataset required by the applicant. In case of application to multiple datasets from different national HDABs, the coordinating HDAB is the most relevant place to apply (**Article 36(1)**).

7.2 Cross-border datasets

For access to cross-border registries or databases, applications must be submitted via the central EU platform. The HDAB in the Member State where the coordinator of the registry is located will manage the application (**Article 76**).

7.3 Multiple datasets in multiple Member States

The central EU catalogue serves as the unified platform for accessing datasets across Member States (**Article 79**). To facilitate the process, national-level catalogues will commonly link to the central EU dataset catalogue, ensuring a unified experience. If users begin their data discovery process involving multiple countries via a national catalogue, the system will **redirect** them to the central EU platform when cross-border datasets are involved (to ensure consistent handling and faster processing).

Application to multiple datasets across Member States may also be done through the local HDAB portals (**Article 67(3)**).

7.4 Data access application form

The data access application form is a critical part of the application process. It ensures that the HDAB can evaluate applicant's needs based on the principles of the EHDS Regulation, including the GDPR data minimisation principle. This form also aligns with the data request form, although the latter is shorter and contains fewer questions.

After selecting the datasets and adding them to the "dataset basket" it is possible to create a new data application or data request.

Tip: Applicants shall name their application as descriptive as possible in the first step. A precise naming practice serves the applicant. Applicants shall consider including, in the name, as a minimum their research question and target population. It should be noted that application title will not be evaluated by the HDAB or affect in the application process.

Once the application is created, applicants will be redirected to the application form itself. The form consists of 10 sections and each of them consists of a different number of questions/input fields, see Figure 1.

Figure 1: Sections of the data access application form in a glance.

The form and the respective sub-sections consist of different types of questions and input requests which essentially differ in the ways the answers should be provided.

Mandatory information is always marked with a red asterisk (*), regardless of the required answering format.

Depending on the respective answers, the form can branch off in different directions, for example, if pseudonymised data processing is requested, more detailed information is required from the applicant.

Key input types in the form:

» **Open or free text answers**

Input from the applicant is required and no answer categories are specified. Applicants can provide their free text responses while obeying the remaining character limit, which will be displayed next to the question once the applicant starts typing.

Figure 2: Project name field of the data access application form.

» **Single- and multiple-choice answers**

For these questions, answer categories are specified from which either exactly one or several can (or must) be selected by the user. Applicants should select one or more predefined options according to the specification in the question.

Figure 3: Example of selection of an option from given list.

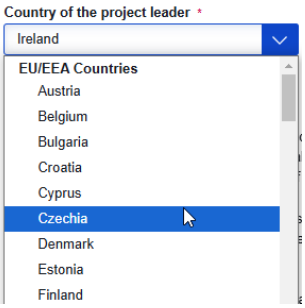
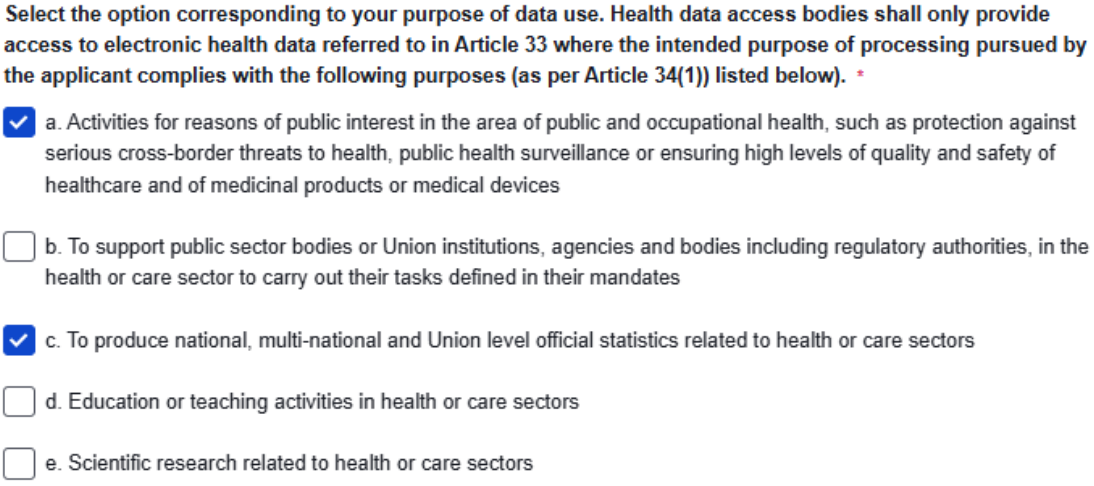


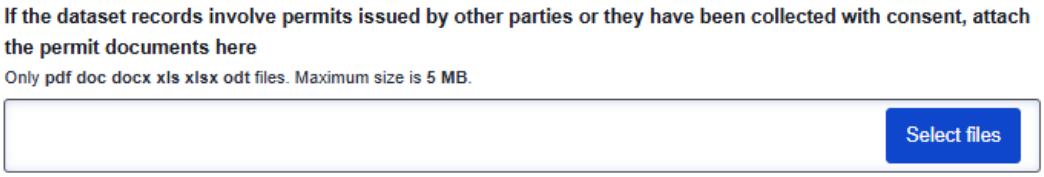
Figure 4: Example of multi-choice answer to a question in the form.



» **File uploads**

It is possible/necessary to upload files/documents at certain stages of the form. The applicant should upload documents as required, such as ethical approvals or financial statements

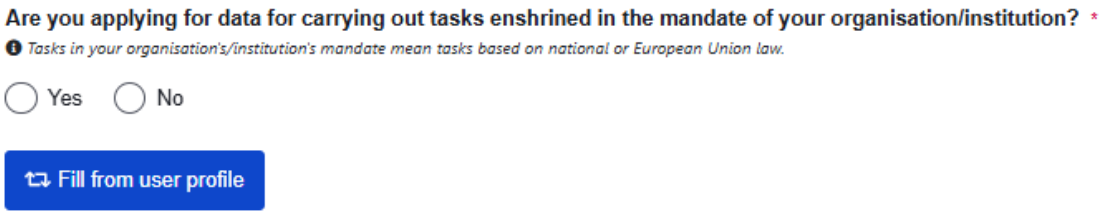
Figure 5: Example of question with possibility to upload a file.



» **Automatic retrieval of information**

At certain input prompts in the form, it is possible to retrieve data automatically. If this possibility is available, it is marked accordingly.

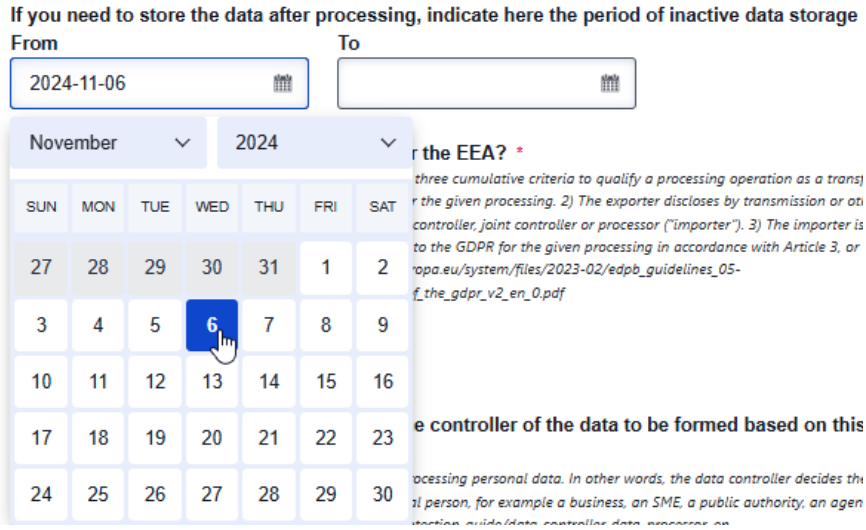
Figure 6: Example of yes/no answer possibility with button enabling filling in the answers from user profile.



» **Date specifications**

Dates are entered via interactive input fields where the respective date can be selected in a calendar view

Figure 7: Example of date selection via interactive calendar.



The sections of the application form are described in more detail in the following subchapters. Applicant will get familiar with the practicalities that should be fulfilled in each section before working with the form online.

7.4.1 Section 1 – Selecting project sources

About this section

Data users should only apply for data that are adequate, relevant and limited to what is necessary in relation to their purpose of use, following the principle of data minimisation of the EU's General Data Protection Regulation58 (Article 5(1c)). The health data access body evaluates carefully if your requirements are in line with the GDPR data minimisation principle.

Why: This section is dedicated to identifying the data sources relevant to the applicant's project.

What: Applicant shall specify the sources of data needed for their project. Once they select the datasets, the field will be filled in automatically.

Examples: This could include registries, biobanks, hospital databases, clinical trial datasets, public health records etc. but only when offered via the dataset catalogue.

Tips: For multi-country projects, applicants shall ensure data from each country are covered. Details for each dataset will be required in Section 6.

7.4.2 Section 2 – Public information of the project

About this section

The health data access bodies in the European Union are obliged to publish information on the data permits, requests and applications on their website within 30 working days after issuance of the data permit or reply to a data request. In this section, you are asked to provide information on your project that can be shared with the public. Make sure this does not include any confidential information. Provide your answers in layperson's terms. As a data user, you will be obliged to make public the results or output of the project no later than 18 months after the completion of the processing or the receipt of the answer to the data request. In addition, you must inform the health data access body of the number of peer-reviewed research publications, policy documents, and/or regulatory procedures conducted using the data accessed via this application.

Why: Comply with public disclosure requirements. This section is dedicated to information on the project that can be shared with the public. The HDABs in the EU are obliged to publish information on the data permits, requests and applications on their website within 30 working days after issuance of the data permit or reply to a data request (**Article 57(j)**).

What: Provide a general overview of the project that is fit for public disclosure, regarding aspects such as:

- Project name*;
- Project leader name*;
- Country of the project leader*;
- Purpose for which the data will be used*;

- The research focuses on the following objectives*;
- Area of research*;
- Description of the data they will use (open question) *;
- Summary of the project*.

Examples: "This project aims to study the long-term effects of chemotherapy on cancer survivors, using anonymised data from the national cancer registers and hospital databases across the Czech Republic, Austria and Netherlands. The research will focus on understanding how chemotherapy impacts the quality of life, mental health and recurrence rates in survivors of breast and colorectal cancers. By analysing patterns in treatment outcomes over a 10-year period covering the years of 2010-2020, the project seeks to identify factors contributing to improved recovery and long-term health. This study will also explore biological sex-specific differences in post-treatment outcomes and inform future clinical guidelines for personalised care of cancer survivors."

Tips: Pay attention to not include any confidential information. Provide answers in layperson's terms.

7.4.3 Section 3 – Applicant and contact person information

About this section

A data permit application should state the name and contact details of the applicant, either a legal or a natural person. Information on the contact person responding to any inquiries related to the application, be it the same person as the applicant or another person, should also be included. If the contact person is not the same person as the applicant, their relationship, e.g. based on an employment contract, should be clarified.

Why: Facilitate communication with the HDAB. Information on the contact person responding to inquiries related to the application will enable better communication with the HDAB. Contact person can be the same person and/or organisation as the applicant or it can be a different person and/or organisation. In case it is a different person and/or organisation the relation to the applicant needs to be specified.

What: Provide detailed information about the applicant and the primary contact person. The information can be filled in automatically from the applicant's user profile, if available.

Example

- **Applicant (Legal person):**
  - Full name*: University of Health Research
  - Street name and number*: 25, Daisy Street
  - Zip Code*: ZP 012345
  - City/Town*: Acme Town
  - Country*: Country X
- **Contact person:**
  - Full name*: John Smith,
  - Email*: john.smith@healthuniversity.eu,

- Phone*: +123456789.
- Name of the organisation*: University of Health Research,
- Business ID of the organisation*: BID12345
- Job title*: Data Coordinator
- Affiliation*: Department of Population Health Studies
- What is the relationship between the contact person and the applicant? *: Employee of the university.

Tips

- An applicant could be either a legal or a natural person.
- What if applicant is not a single legal or natural person? If you are, for example, a consortium of universities and research institutions from different EU member states, please decide who is the lead applicant and fill in the application accordingly.
- If the applicant is a legal person then the contact person is a natural person that has some affiliation to the applicant.
- If the applicant is a natural person, they are also considered the contact person for the application.

7.4.4 Section 4 – Payment details

About this section

Payment details of the person to whom the health data access body addresses the bills related to this application and the consequent data permit, if granted.

Why: Enabling billing for fees related to the application. The fees are used to cover the work to assess applications, prepare datasets and provide access to SPEs (**Article 62**).

What: Provide information on payment details of the person and/or organisation to whom the HDAB addresses the bills related to this application and the consequent data permit, if granted.

Example

- Full Name *: Jane Doe
- Postal Address *: 123 Health Drive, Suite 45x, Wellness City, Country
- Phone Number *: +123 456 789
- Email *: jane.doe@example.com
- Invoice Type (Paper/Electronic) *: Electronic
- Invoice Reference Number *: 789XYZ123
- E-invoice Address (IBAN) *: FI21 1234 5600 0007 85
- Operator ID *: OP123456
- Name of the Organisation *: HealthData Inc.
- Business ID of the Organisation *: 9876543210
- VAT Number *: FI9876543210
- Peppol Code (if applicable): 0192
- Is the Project Financially Covered? *: Yes

- Range of Amount of Financing *: 50,000 - 75,000 Euro

Tips

- Choose the preferred invoice type carefully. If electronic, ensure EDI or IBAN and operator ID details are correct.
- Clearly state if the project is financially covered. Be transparent if funding is not yet confirmed.
- If unsure about details like Business ID, VAT number, or Peppol code (Identifier for Pan-European Public Procurement Online), applicants shall consult with their financial team and promptly update any changes in contact and/or financial information before the submission to avoid miscommunication and delays.
- Ensure that the information provided matches supporting documentation they have provided with the application, such as contracts or financial agreements. Inconsistent details can cause complications.
- Carefully review the entire section before submitting to catch any potential errors or omissions. It can save time and prevent delays in the application process.
- The Invoice Reference Number is not necessarily a number but any information how to make sure the invoice is correctly routed at the invoice recipient.

7.4.5 Section 5 – Purpose of planned data use

About this section

Applicants should indicate the purpose for which data are sought. According to the EHDS Regulation proposal **Article 53**, the proposed valid purposes for secondary use of electronic health data are: Applicants need to explain and argue why the requested data are necessary for their indicated purpose of use. Applicants are also asked to provide information on the aim of the project. Then, depending on the use purpose (research or not research), applicants need to provide a summary of the plan for using the data or a summary of the research plan, and information on the person responsible for the data use or research

Why: This section aims to collect the information to evaluate whether the requested data can be ethically and technically provided for the planned purpose, ensuring alignment with EHDS-approved purposes and data minimisation principles, as well as the ethical implications of the planned use.

What: The application or request should state clearly which purpose the health data is to be used for. This is essential as any secondary use must comply with EHDS approved purposes (see 6.3 Allowed purposes for secondary use of health data). Any planned purpose not complying, is to be denied/rejected (see Prohibited purposes).

Applicant must justify the necessity of the data and its amount, describe their project's aim, expected benefits including societal impact and provide details about the person responsible for data use.

Additionally, applicants will need to submit a summary of their research plan and specify the format of the electronic health data (anonymised or pseudonymised).

Example: Below is an example justification of the need of personal electronic health data in pseudonymised form:

> This project aims to explore sex differences in the management and outcomes of Type 2 diabetes in individuals aged 18–65 years across three Member States. By analysing longitudinal, personal, pseudonymised health data, we will assess how treatment adherence and comorbidities affect long-term health outcomes, such as cardiovascular events.
>
> Anonymised data are insufficient, as we require linking multiple datasets across national registries at individual-level, which necessitates pseudonymised data to maintain continuity between observations. All data will be processed in an SPE with strict access controls, ensuring compliance with GDPR and EHDS principles. Results will inform clinical guidelines for personalised diabetes care and support policymaking on chronic disease management.

Tips on how to determine the use purpose

- Refer to the list of permitted purposes provided in the application form.
- Clearly state why anonymised or aggregated data is insufficient for your objectives, if applicable.
- Ensure the intended use aligns with the Regulation by explaining how it contributes to public health, research or societal benefits.
- Do not use health data in ways that could have negative social, ethical or economic implications.

7.4.6 Section 6 – Description of the data needed

About this section

In this section, you need to provide a description of the requested dataset record, clearly indicating which dataset records the application concerns. You should only apply for data that are adequate, relevant and limited to what is necessary in relation to your purpose of use, following the principle of data minimisation of the EU's General Data Protection Regulation58 (Article 5(1c)). The health data access body evaluates carefully if your requirements are in line with the GDPR data minimisation principle.

Why: Data holders and the HDABs (from different Member States) evaluating the application need to understand the data needed/applied for. The description provided in this section is necessary for the HDABs to assess whether the application is in line or not with GDPR and EHDS Regulation.

What: Provide a description of the required data for each country/HDAB that is a provider of the datasets that applicant have included in their application.

Figure 8: Screenshot for section 6 – application involving multiple datasets from multiple countries/HDABs

As an overview of the data being applied for, the application form will display, per country, the list of the data included in the application and the list of HDAB(s) that will receive the application. If the applicant has already been in contact with the respective HDABs, they should provide the contact details; this information would help the application be forwarded to the appropriate persons. Applicant should also describe their data linkage plan, meaning how they will link data they obtain from various sources, e.g. based on a personal identification code or through subject similarity metrics.

Subsection 6.1 - Defining data extraction criteria

Applicant will be prompted to define the criteria for their **study cohort**. This is crucial as the data holder will use these criteria to prepare the necessary datasets.

The study cohort can be established using:

- criteria from the application form;
- a previously established cohort (e.g., from an earlier healthcare-research study);
- a combination of these options;
- the entire population of a country, state or other area.

For all these options, applicant will need to answer a core set of questions.

- Applicant must explain whether data subjects have been informed about the planned data use and if not, describe the transparency measures they will implement. While individual notification is not required under the EHDS Regulation for secondary use, transparency about the project (e.g., through public websites or registries) is essential to ensure compliance with GDPR and national guidelines, and Article 58 of the EHDS Regulation.
- If applicant has an ethical review from a national or institutional ethics board, they should include it in this section if relevant for the use-case. Note that local approval does not apply for another country.
- Specify the data variables to be used during extraction by referring to the descriptions in the data holder's metadata catalogue or data dictionaries.
- Indicate the size of the required study cohort (exact or estimated) and justify this size.
- Specify the time period for the data needed.
- Describe the required extraction method (random sample, all qualifying individuals, or other) and provide the inclusion and exclusion criteria.
- If the data will be extracted **multiple times**, specify the required frequency or time points.

- If the order in which data are extracted from different data holders affects the composition of the cohort, please specify the expected sequence of extraction.
- If applicant's **study cohort is based on a previously established cohort,** then the applicant will need to provide details on this prior cohort. Specifically, whether the cohort has been formed based on informed consent, detailed description of the legal documents that underpin the previous cohort formation, including permits and/or informed consent and finally they will be asked to identify the contact person who will be responsible for delivering the study cohort information to the relevant HDAB. This person could be, e.g. the Principal Investigator/Clinician from the previous study or a contact of the Trusted Third Party with access to the prior study's cohort composition.

Subsections 6.2 and 6.3 - Groups of controls and relatives

Among the extraction criteria the applicant defines for the study cohort, they can:

- **re-use** the data variables, required time periods, extraction method, extraction periodicities and extraction order for the controls and relatives;
- they can **re-define** the criteria for these groups if needed.

Also, for controls and relatives, applicant will be asked to specify the size of these groups and their inclusion and exclusion criteria and information on previously issued permits (if any) that serve as the basis for the formation of control and relative groups.

Examples of data minimisation

- Age ranges (e.g., 18-21 years, 21-24 years, etc.) instead of exact ages and dates of birth. If knowing the exact age or month of birth is essential, then applicants shall provide justification. Additionally, applicants shall specify which variable requires the exact age information.
- Among multiple attributes that could serve the same purpose or could substitute each other, request only one. For example, patient's blood pressure readings or their heart rate. Both attributes can provide insights into the patient's cardiovascular health, but to serve the purpose of assessing their general health status only one is needed.
- Time ranges instead of exact time points e.g. month of clinic visit instead of exact date.
- Racial or ethnic origin related information shall be included only when the lack of that information would make applicant's study goals unachievable.
- Data sample when, e.g. a whole population is not necessary for realising applicant's aims.

Tips

- Apply only for data that are adequate, relevant and limited to what is necessary in relation to the purpose of use. Do not request data variables for which they would not be able to justify its necessity for the project. Applicants shall ask themselves "why do I need this variable?" - and if they do not have a valid response, they shall leave that variable out from their application. A response such as "it might be useful later" is not in line with data minimisation (**Article 66**).

- Ensure the amount of data they request is adequate but not excessive.
  - Be aware that if a data user requests changes after the permit has been issued (e.g., extending the permit duration or modifying the dataset), additional fees may apply to cover the costs of these adjustments. More information in TEHDAS2 Milestone 7.1 Draft guideline for data users on how to use data in a secure processing environment.
- Consider the privacy impact of each data element.
- Request only the necessary number of records. If applicant needs data for an entire country's population, they shall clearly justify why data of this scope are required.
- Check with their national data protection authority on the possible ways of implementing GDPR requirements on data subjects' rights, concerning particularly of rights to information. If applicants are organisationally affiliated, they shall request support from their Data Protection Officer (DPO) if their organisation has one.

7.4.7 Section 7 – Other data to be combined

About this section

It is possible to combine other data, such as data in your possession or data obtained from elsewhere, with the data applied for with this application. List the information for all additional data that will be combined with the data authorised by the health data access body. If you later want to combine data with the data authorised by the health data access body, you need to submit an amendment application to the same health data access body. If you have any other data in addition to the study cohort that you would like the health data access body to combine with the data you are applying for, you will receive instructions on how to deliver the data securely after the permit has been granted.

Why: Provide details on datasets the applicant already possesses or obtained from other sources outside the EHDS infrastructure. This information ensures the HDAB can evaluate the compatibility and compliance of these datasets with the data they are applying for.

What: Provide the following details about the existing dataset(s) that applicant wants to have combined with the dataset(s)they are applying for.

- What is the country/countries of origin*.
- Who is the data holder(s) *.
- Describe the database(s)/registry/registries*.
- Describe the dataset **r**ecord(s)/register/registers *.
- To the extent applicable*:
  - dataset
  - number of the files
  - format of the files
  - size of the files
  - special notes (are there direct/indirect identifiers, data should be pseudonymised, etc.).

Share any other data permits issued for the same project within the EHDS infrastructure or outside the EHDS infrastructure. The permits must be valid at the time data are processed. In this case provide the following information:

- Issuer, date of issue, expiry date, identification information.
- If the datasets were collected under prior authorisations (e.g., research ethics approvals) or participant consent, attach the relevant approval documents and/or blank templates of the consent forms or information sheets. Do not include filled-in forms containing personal information, only blank templates.

Examples

- Combining real-time data from wearable devices (e.g., heart rates, activity levels) collected by a current project with historical health data from a completed research project. This integration will allow enhanced analysis of cardiovascular health, enable longitudinal studies by providing continuous monitoring and help develop personalised health recommendations based on comprehensive insights.
- Genomic study combining DNA sequencing results from a biobank with electronic health records to investigate correlations between genetic markers and treatment outcomes for chronic diseases.

Tips

- Plan ahead: Applicants shall consider this section thoroughly because if they decide later to combine additional data with the data authorised by the HDAB, they need to submit an amendment application to the same HDAB, incurring additional fees.
- Applicants shall use this section to inform the HDAB if they want to use other data in their possession to be combined with the datasets they are applying for.

7.4.8 Section 8 – Data processing, data protection and safeguards to prevent unauthorised use of data

About this section

According to the EHDS Regulation proposal Article 50(1), the health data access bodies shall provide access to electronic health data only through a secure processing environment (SPE).

Why: Given the need for high-level protection when processing health data, the technical requirements for the infrastructure where the data will be worked with, once access is granted, are addressed in this section of the application form. HDABs will provide access to (individual-level) electronic health data exclusively through an SPE. The technical specifications like hardware specifications and analytical software needs may vary based on, e.g. data formats, analyst skills/preferences and planned analyses. Specifying computational needs in advance helps the HDAB identify the SPE best fit for purpose. As the GDPR applies for the sharing of personal electronic health data, this section also includes questions to ensure compliance with GDPR requirements.

What: Applicants must provide details on the below*.

- The SPE requirements

  - Computational needs (e.g., RAM, processors, storage, software).
  - SPE provider (if known), including name and web address.
- Data access timelines
  - Specification of when they need access to the data considering the project schedule.
  - If the application involves datasets from multiple permits, ensure the timelines align to optimise workflows and avoid delays (for additional details see Expected timeframes from data application to data access)
- Data transfers outside the EU/EEA
  - Indicate if individual-level data will be transferred outside the EU/EEA, including through remote access.
  - Note: Even accessing data from a third country is considered a transfer and must comply with Chapter V of GDPR. In case of doubt, applicants all refer to their DPO.
- Cold storage needs
  - Indicate whether processed data needs to be retained in cold storage for compliance with research retention policies.
  - Note: Cold storage refers to long-term storage within the same Secure Processing Environment (SPE). EHDS regulations strictly prohibit the extraction of data from the SPE.
  - Specify the duration of storage and justify its necessity (e.g., for reproducibility, audits or compliance with research integrity policies).
  - All cold storage data must remain securely stored within the SPE, with access restricted and auditable.
- Data controller identification
  - Identify the data controller for the processing of health data based on the application.
  - For individuals, this is the applicant.
  - For organisations, it is the organisation itself.
  - Note: Under the EHDS Regulation, HDABs retain overall control of the shared data, ensuring its use complies with regulatory safeguards.
- Individuals with access
  - Provide complete list of all individuals who will require access to the dataset in the SPE. Only these individuals will be included in the data permit if the application is approved.
  - This list can be updated later however this will require an amendment to the access application.

The applicants will be asked to confirm various statements documenting their commitment to key data protection obligations, including security. These statements are based on applicable EU laws, which are enforceable and auditable. By ticking these checkboxes, applicants confirm their understanding and acknowledgment of the obligations and prohibitions that will apply if their application is approved. These obligations are enforceable under applicable EU laws, including the GDPR and EHDS Regulation. While ticking the checkboxes does not create a new legally binding contract, applicants remain subject to all legal and regulatory requirements related to the use of health data.

Examples

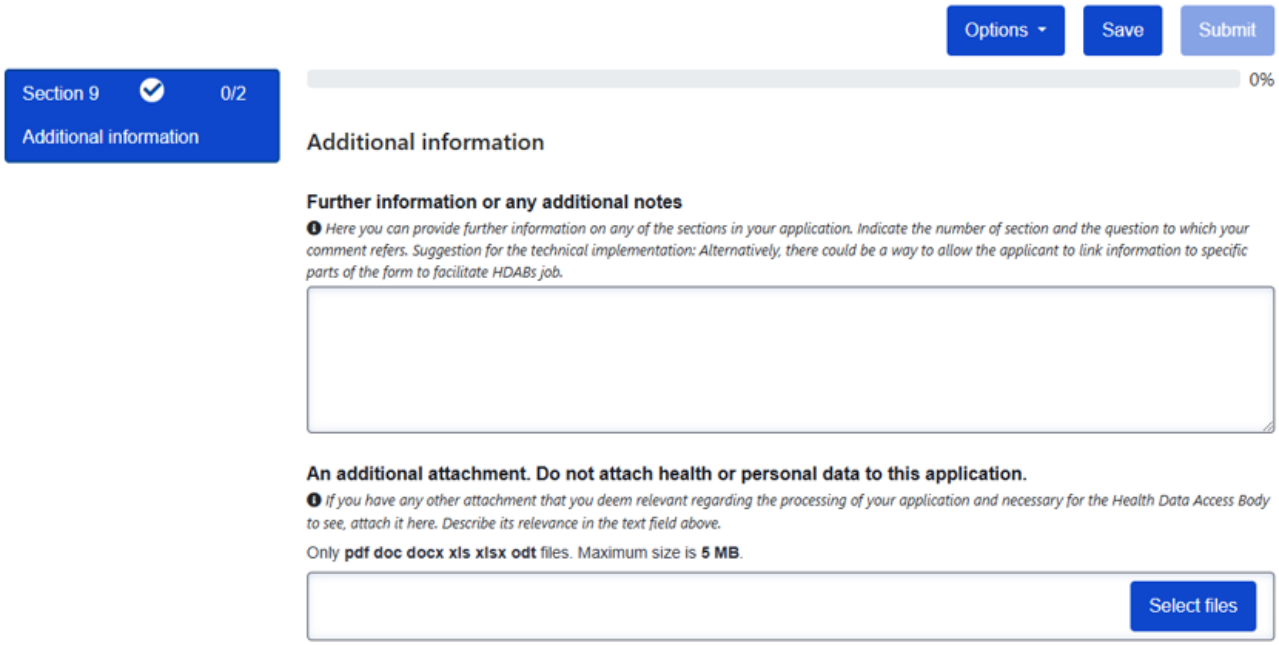
- Analysing omics datasets may require more computing resources, whereas basic statistical analyses on tabular data may need less, ultimately affecting the associated fees and potentially the choice of the SPE.
    - E.g. tabular data analysis may require fewer resources, such as 8GB RAM and standard statistical software like SPSS or Stata.
- Machine specifications depending on the complexity and volume of applicant's operations; applicants shall specify the following characteristics.
    - RAM: the memory needed for applicant's analysis. Intensive data processing often requires more RAM.
    - Processing Units (CPU/GPU): the number and type of processors required, especially for computationally demanding tasks.
    - Storage: adequate space for both data and software, particularly for large datasets.
    - Operating system: Linux, Windows or other operating system compatible with the software and tools to be used.

Tips

- Applicants shall be precise and detailed in the description of desired SPE, including statistical software (SPSS, Stata, R), programming languages (Python, R), IDEs and notebooks (JupyterLab, RStudio), image visualisation and annotation tools (Cytomine, OHIF Viewer) and documentation tools (Microsoft Office, Adobe Acrobat Reader), among others.
- It is essential to identify applicant or their organisation's role under the GDPR and the related obligations. Refer to EDPB guidance on data controllership here. If the applicant is affiliated with an organisation, they shall seek support from their DPO.
- If the applicant needs the data to be made available later, they shall indicate it in this section. Applicant may request to receive the data later, e.g. to coordinate the arrival of datasets from multiple permits into the SPE or to better align data availability with their project timelines.
- Data transfers – applicants shall determine if their project involves transferring individual-level data outside the EU/EEA and understand the obligations under Chapter V of the GDPR. Accordingly, they shall consult their DPO or legal team early if they have any doubts or questions.
- Cold storage – applicants shall plan for data retention requirements and justify the duration for cold storage.

7.4.9 Section 9 – Additional information

Figure 9: Screenshot of the complete Section 9 of the application form.



Why: The application form was designed in a way to be as comprehensive as possible, using a combination of pre-defined response options (for the sake of consistency) and free text fields (for the sake of flexibility and explainability) to ease the work of the HDABs when evaluating the responses. Yet, applicants may still feel that they have relevant information about their project which, if they could share it with the HDAB, increases the likelihood of approving their application and gaining access to the data. While responding to these questions is not mandatory, applicants are free and encouraged to provide any such additional information to support understanding the intention of their application, its desired outcome and approval. Providing this information, though optional, may strengthen the applicant's case by clarifying unique project requirements, justifications or existing agreements with other stakeholders.

What: Anything that is relevant, necessary or complementing the application without repeating information already provided, in the form of free text and optional document upload. Applicants shall identify the relevance of the information, in addition to the section and question number that they are amending or explaining further.

Examples

- Further information on applicant's planned data extraction order.
- More information about the data to be combined.
- Any agreements made with other parties (e.g. data holders) regarding data extraction.
- Additional reasons for choosing a particular SPE provider, including technical, security or financial considerations.

Tips:

- Applicants shall be concise and relevant: Provide only information that adds value to their application without overloading it. Ensure that they supply just enough information to explain the project's needs effectively, but don't overload the HDAB.
- Align with previous sections: Ensure that any additional information complements and expands upon earlier form responses rather than duplicating them.
- Anticipate questions: Consider areas where the HDAB might require further clarification or where additional context could enhance the understanding of the application.

7.4.10 Section 10 - Confirmation of information

About this section

Before this application is processed, you as the applicant must approve processing fees. To add information on the prices and the maximum price estimate for data extraction once available.

Why: To ensure that the applicant is aware of the potential financial consequences of submitting the application and that they confirm the accuracy of the provided information is recorded - which, in case of providing false and misleading information intentionally, may have an impact on the sanctions to follow.

What: The statements to be confirmed focuses on 2 aspects.

- Financial implications
  - Applicants shall be aware that application fees are calculated based on administrative and technical costs incurred by the HDABs. Even if the application is withdrawn after submission, fees for services already provided (e.g. dataset preparation, review) may still be charged.
- Accuracy of information
  - Inaccurate, incomplete, or false information may result in:
    - delays in processing the application;
    - refusal of the application;
    - penalties, including fines or legal actions, depending on the severity of non-compliance.
  - The HDABs are mandated to monitor and supervise compliance, including reviewing the accuracy of the application and the implementation of the respective data permit.

Tips

- While it is foreseen that after many hours of work invested into completing the form, applicants would like to submit it as soon as possible, the weight of confirming these statements should not be underestimated. Applicants shall take time, if necessary, to double-check the completeness and accuracy of the responses provided.
- Applicants shall familiarise themselves with the fee structure and non-compliance penalties to avoid unexpected financial or legal consequences. Get more

information about this topic in TEHDAS2 “Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS Regulation”

- Applicants shall be transparent – if there is uncertainty about any information (e.g., technical requirements or project timelines), they shall provide a clear explanation or note to avoid misunderstandings.

8 Terms and conditions of use

Structured procedures and conditions of the EHDS Regulation are designed to facilitate the responsible and secure use of electronic health data (EHD) within the EHDS, balancing the benefits of data utilisation with the imperative of protecting individual privacy and data security. This requires the applicant to comply with certain terms and conditions when being granted access to data. These terms and conditions are binding before any access to electronic health data is granted.

8.1 General obligations and prohibitions

Article 61 of the EHDS Regulation and other provisions set out further duties and obligations of data users in the context of using data. These requirements generally apply to all forms of access: data permits, including making data accessible in SPEs, as well as approved health data requests.

Table 1: Overview of health data applicant’s expected behaviours and actions (do’s) and the prohibited or discouraged behaviours (don’ts).

DO (=shall)	**DON’T** (=shall not)
• Maintain high level of data protection and safeguards to prevent unauthorised use of data. • Ensure applicant expertise and adequate technical measures. • Inform HDABs of any significant findings related to the health of natural persons. • Cooperate with HDABs in the application clarification (e.g. purpose of the use of data, the sampling method, responsibilities) • Keep contact and user information updated. • Acknowledge the sources of the EHD and the fact that the EHD have been obtained in the framework of the EHDS.	• Process EHD beyond the permit’s scope, especially for any prohibited purposes. • Share access to the EHD, or make those data available, to unauthorised third parties not mentioned in the data permit. • Re-identify or attempt to re-identify the natural persons to whom the EHD made available relates. • Download data from the SPE without specific agreement/permit from the HDAB. • Do not connect to the SPE from outside the EU, this is transferring data to a 3rd country. • Do not use a VPN to fool the system. • Do not provide their username/password to anyone. Access is individual and actions monitored. Do not carry out studies/analysis that were not included in the permit.

• Request an amendment to the permit when a new user needs access to the SPE. • Get familiar with the provisions of EHDS and GDPR when handling personal data, particularly when it is highly sensitive (e.g., Genomics). • Inform the HDAB in case of errors in the access process. Make sure that the software used in the SPE is allowed. Inform HDABs when a dataset has been enhanced and can be given back to the data holder, providing all the necessary information.	

Examples

- While processing pseudonymised data in the SPE and applying their algorithm, applicant observes factors which substantiate a diagnosis of lung cancer that has not yet been recorded. The applicant must inform the HDAB, providing relevant facts, to allow the HDAB to identify the person and take the necessary steps.
- Once the applicant has obtained a data permit and access to the requested data in the SPE, they must publish an output with the (anonymous) results of their research 18 months after finishing the processing in the SPE (Article 61(4)). In this, the applicant must indicate in the report that the data was obtained through the EHDS.

8.2 Data permit

A data permit (**Article 68**) is an administrative decision issued by an HDAB, granting a health data user the right to process specific electronic health data for defined secondary use purposes. It also instructs the data holder to make the specified data available. Data permits are limited in time (up to 10 years), scope and purpose, with all terms and conditions outlined in the permit. If the permitted use needs to be adjusted, the health data user must request an amendment to the permit.

8.3 Agreement with data holders

In certain circumstances, data access may affect intellectual property rights or trade secrets. This may lead to rejection of the application, or to the need for additional specific conditions. Direct contractual arrangements may be necessary between health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets. To facilitate such agreements, the Commission will provide non-binding model contractual terms for use by stakeholders (**Article 52(4)**).

Example: Data is needed for a study on the effectiveness of a new cancer treatment. Sensitive information from clinical trials conducted by a biotech company is included. A direct contractual agreement is required to ensure the protection of intellectual property while access to anonymised data is allowed.

8.4 Approved data requests

The HDAB provides responses to approved requests in an anonymised statistical data only. Health data users must follow general obligations and maintain safeguards to prevent misuse, see General obligations and prohibitions.

8.5 Making outcomes and results available

According to **Article 61(4)**, data users are required to publish the results or output of the secondary use of electronic health data (EHD), including information relevant for the provision of healthcare. The results or output of secondary use shall contain only anonymous data.

Health data users should inform the HDABs from which a data permit was obtained about the results or output of secondary use and assist them to make that information public on the HDABs' websites. Such publication shall be without prejudice to publication rights in scientific journals or other scientific publications.

Publication must acknowledge the sources of the electronic health data and the fact that the electronic health data have been obtained in the framework of the EHDS.

8.6 Fees

Based on **Article 62** of the EHDS, the HDAB shall inform the applicant of the expected fees that will be charged to assess the application, prepare the data and provide the data in a SPE for its processing. A processing fee will be charged for processing the application and will also apply in case of a cancelled application or a negative decision. In multicountry applications or requests, each country will send their fees and the applicant will have to pay each of them separately in country's respective platform. More details about fees are available in TEHDAS2 "Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS Regulation".

8.7 Liability and sanctions

HDABs monitor compliance with the terms of the data permit and are authorised to:

- revoke permits in cases of non-compliance;
- impose penalties to data users and data holders, such as fines or restrictions on future access.

Health data users can appeal the HDAB decisions in accordance with national procedures. More details about penalties are available in TEHDAS2 “Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS Regulation”.

8.8 Data quality

Health data user should be aware that the HDAB will make available EHD collected from various stakeholders of the health and care sector. It cannot be guaranteed that such data:

- are coherent in terms of formats, coding, nomenclatures and other criteria;
- fully comply with the specific needs of the health data user;
- meet the data quality expectations of the health data user.

This applies even when this is not specifically mentioned in the data permit.
Datasets made available through health data access bodies may have a Union data quality and utility label applied by the health data holders (**Article 78**). If the data were collected with public funding, it must have this label. The label includes details like where the data came from, how accurate it is and how it was managed.

Data users are responsible for assessing and managing data quality issues during their analysis.

9 Expected timeframes from data application to data access

There are several procedures how to get from the data application submission to results publication. Figure 10 illustrates and describes the timeframes for each procedure. The specific procedure an applicant follows depends on the chosen dataset from the EU dataset catalogue and the responsiveness of all stakeholders involved in the process, including the HDAB, the health data holder and the applicant.

Figure 10: Different workflows possible within the HealthData@EU infrastructure and expected timeframes and duration of each step of the workflows.

In a standard data access application, the HDAB has 3 months to issue a permit, the data holder has 3 months to prepare the data and the HDAB has 2 months to make the data available in the SPE. The data user then has the time specified in the permit to analyse the data and 18 months to publish the outcomes.

For public sector requests, the HDAB has 2 months for application consideration. If a trusted data holder is involved, the steps differ slightly, but the overall timeframe is similar.

For data requests, the HDAB has 3 months for decision-making, the data holder has 3 months for data preparation and statistical results are shared within another 3 months.

In all scenarios, the data user has 18 months to publish the analysis outcomes. Additionally, there are 4 weeks to complete the application form if requested by the HDAB. A complete application may lead to data access in less than 8 months.

9.1 HDAB application consideration

Once a data access application is submitted to the relevant HDAB, the application consideration phase begins. For complete applications, where no further information is required from the applicant, the HDAB has a time limit of 3 months to consider and respond to an application by either issuing a permit or rejecting the application (**Article 68(4)**). The

consideration phase can be extended to a maximum of 6 months, when more time is needed by the HDAB to examine the application and after timely communication to the data applicant.

9.2 Accelerated procedure

There are specific circumstances under which the HDAB application consideration is accelerated: these comprise requests from public sector bodies, Union institutions, offices and agencies with legal mandates in the field of public health. Under these circumstances, the HDAB has a time limit of 2 months after receiving a health data access application to either issuing a permit or rejecting the application (**Article 68(6)**). The consideration phase can be extended to a maximum of 3 months in case the HDAB requires more time to evaluate the accelerated health data access application procedure.

9.3 Applications involving trusted health data holders

If a trusted data holder is involved, the steps differ slightly, but the overall timeframe is similar (see Figure 10). Applications that cover electronic health data held by trusted health data holders responsible for evaluating the data access application and issuing a positive or negative assessment up to 2 months after receiving the data access application forwarded by the HDAB. The assessment made by the trusted health data holder will be sent to the HDAB, that has 2 months to evaluate the assessment made by the trusted health data holder. The HDAB is the ultimate instance responsible for issuing the permit (in case of a positive assessment) or rejecting the application, as well as for informing the applicant of the outcome of its application. Under this procedure, the consideration phase takes up to 4 months in total. In case a permit is granted, the trusted health data holder will prepare the data (as described in 9.6) and make them available for use on its SPE, with no intermediation by the HDAB (the step 9.7 does not apply). The conditions for data user analysis are as described in 9.8.

9.4 Additional information may be asked by HDABs

In case the information in the application is deemed incomplete or is not of sufficient detail, the HDAB can request additional information from the applicant. When additional information is requested, the time that the HDAB has to assess the application is paused until the required data is received. Applicants have 4 weeks to respond to the information request of the HDAB. If the applicant fails to provide additional information within this 4-week maximum timeframe the application may be rejected. If the application is rejected, the applicant will still be subject to pay any fees incurred during the process.

9.5 Decision on data use permission

HDABs are tasked with deciding on health data access applications and issuing administrative acts, i.e. data permits. The table below provides a summary of the possible HDAB decisions and the next steps relevant for the HDAB and applicant.

Table 2: HDAB decisions with possible scenarios as the next steps.

HDAB decision	Next step(s)	
	HDAB...	**Applicant...**
Applicable fees	• Informs Applicant about the fees covering the overall processing of the health data within the EHDS infrastructure (**Art 62(5))** – for more details about fees see TEHDAS2 Deliverable 4.1.	• Decides whether to accept or withdraw the application, e.g. due to lack of funding available to cover all fees. If the applicant withdraws the application, s/he shall only be charged the costs that have already been incurred.
Issues a data permit	• Publishes information about the permit granted within 30 days of the issuance and maintains internal record about the permit. • Engages the health data holders and the SPE provider.	• Becomes "health data user" with all relevant rights and obligations.
Rejects the application	• Justifies its decision (**Art 68(9))**. • May decide to provide a response in an anonymous statistical format if the Applicant agrees to that approach (**Art 68(3)**). • Publishes information about the rejection within 30 days and maintains internal record **(Art 58(1))**.	• May resubmit the application, taking into consideration the HDAB's justification. • May contest the decision via the established channels.
Application is incomplete (**Art 68(4))**	• Notifies the applicant about incomplete application. • The application clock is frozen for a maximum of 4 weeks.	• Completes the application within 4 weeks, otherwise the permit is not granted.
Revisions or amendments to the data permit	• If modifications to the permit are needed by either the applicant or the HDAB, a formal amendment process must be initiated. • The amended permit will include updated conditions, data specifications or timelines, subject to regulatory requirements.	
	• Approval is at the discretion of the HDAB.	• Applicants must provide a justified reason for the amendment.

The permit's content is pre-defined in the Regulation and will contain the description of the data to which access is granted, the duration of access, technical characteristics and tools, specific conditions and the fees to be paid. The permit enables the health data user to process the data, as specified in the permit, for specific secondary use purposes based on the Regulation's and the permit's conditions.

9.6 Data preparation

After the data permit is issued, the HDAB will immediately request the data from the health data holder(s). The data holders have 3 months to send the data to the HDAB and in some cases, this period can be extended by another 3 months (**Article 60(2))**. The data preparation period is reflecting the requirements of the data applicant written in the health data access application form. During this time frame the health data holders will be extracting the data following the data minimisation and purpose limitations rule (**Article 66**). Then, the HDAB will have 2 months to prepare it, link it, clean it, pseudononymise it and share it in the SPE.
When datasets involve data from multiple countries, the same timeframes (up to 6 months total) apply for preparation. Coordination among HDABs does not extend the preparation period, though applicants should anticipate potential complexities.

Tip: When applicants apply for more datasets from more multiple countries, they can specify in which SPE the data should be analysed already in the data access application form, see Section 8 – Data processing, data protection and safeguards to prevent unauthorised use of data and TEHDAS2 Deliverable 7.1 "Guideline for data users on how to use data in a secure processing environment".

9.7 HDAB makes health data available

The HDAB shall make available the electronic health data to the health data user in a SPE within **2 months** after receiving them from the health data holders, unless the HDAB specifies that it will provide the data within a longer specified timeframe.

9.8 Data user analysing data

Once the data are shared with the applicant the data use phase starts and the applicant becomes a health data user. HDAB makes the datasets comprised in granted data permit available to the data user in the dedicated SPE. Please review the following documentation and guidelines to get better insight into the data analysis phase:

- TEHDAS2 "Guideline for data users on how to use data in a secure processing environment";
- TEHDAS2 "Guideline for data users on handling research outcomes".

Data users have the amount of time specified in the data permit to process the data in the SPE (this amount of time can be up to 10 years). After completing the analysis, they have 18 months to publicly share the results (**Article 61(4)**). The data from the SPE will be archived

by the HDAB for reproducibility reasons enabling a reanalysis of the data if needed for instance in peer-review processes.

Health data users can apply for extending the data permit duration. The HDAB considers whether the extension can be granted. The extension requires an amendment and may incur an additional fee. Note that only one extension of a permit is possible.

10 Notice for public consultation – Known time dependencies on the other TEHDAS2 tasks and joint projects

1. Applicants can request data that includes information from people who have opted out. This should be explained in the appropriate section, but it hasn't been covered yet. This milestone builds on the draft version of the common application form developed under the EHDS2 Pilot project, which was created before the final regulation was adopted. This issue will be addressed after the public consultation.
2. What does it mean a "finished" research project – it would have to be defined. Answering a research question will be followed by a publication for which access may still be needed to create, e.g. figures and graphs. Then access may be needed as part of the **reviewing** process.
3. Dependency on **Data access application template** within T6.3 (planned for April 2025 as part of 4th release of the Central Services)
4. Need links to the following guidelines once available:
    a. D4.1 - Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS Regulation (Chapter 5.6);
    b. D7.1 - Guideline for data users on how to use data in a secure processing environment;
    c. D8.4 - Guideline for data users on handling research outcomes.
5. When a data holder has a data quality and utility label, but quality is deemed poor, can the data user report somewhere? At the HDAB?
6. Dependency between data description by applicant and what data holder or HDAB needs
    a. Section 6 of the application form is very relevant for the data holders (task 6.1). How specifically will applicants describe the data needed? Will it be linked to the metadata provided by the data holder? Would it be possible to upload a protocol? Would a researcher write a short text or tick boxes per variable? Would they be able to request "free text". For the data holder, it would be very useful to have a detailed description of the requested variables.
7. Should data applicants evaluate the identification-risks of merged data if asking for combining data?
8. Considering user stories for better explanation of situations which applicant may expect.

11 Appendix 1: User journey

When a data user applies for electronic health data for secondary use purposes, such as research and innovation activities, education and policymaking, within the European Health Data Space (EHDS), the user journey consists of several stages (see Figure 1). Access for certain purposes (public or occupational health, policy-making and regulatory activities and statistics) is reserved for public sector bodies and Union institutions (see Chapter IV, Art. 53(1) and 53(2)).

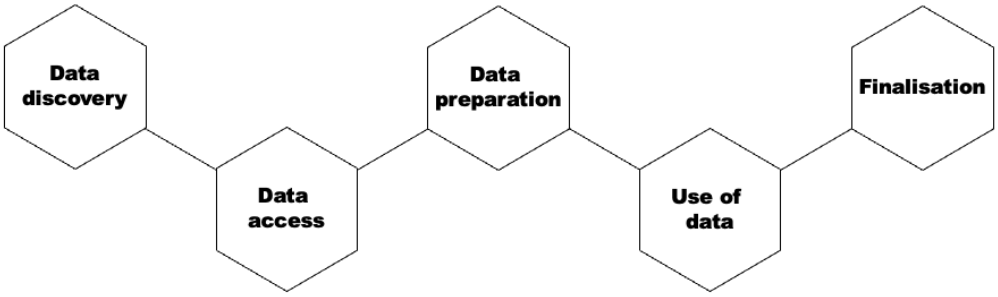


Figure 1: EHDS user journey consists of five main phases: data discovery, data access, data preparation, use of data and finalisation.

11.1 Data discovery

Before being able to use the data, the user needs to investigate whether the data needed is available and whether it is available in the necessary format for the secondary use purpose. This phase is called data discovery. Datasets available in the EU can be found in a metadata catalogue at *https://qa.data.health.europa.eu/*. Once the data discovery is completed, the user can begin the process of applying for the data.

11.2 Data access

In the data access phase, the user fills in and submits a dedicated and standardised data access application form or a data request to a health data access body (HDAB)ii. The user must complete the information required in the form, upload necessary documents and provide justifications as needed.

Data access application form is used when the user seeks to use personal level data. Data request is for cases when the user wants to apply for anonymised statistical data.

11.3 Data preparation

During this phase, the data holder(s)iii deliver(s) the necessary data to the HDAB, which starts to prepare the data for secondary use. Techniques for pseudonymisation, anonymisation, generalisation, suppression and randomisation of personal data are

employed. The data minimisation principle (as per the GDPR) must be respected to ensure privacy.

11.4 Use of data

In this phase, the user performs analyses based on the received data for the purpose defined in the application phase. Analysing personal level data must be performed in a secure processing environment. The duration of this phase is specified in the Regulation (**Article 68(12)**).

11.5 Finalisation

This last phase of the user journey concerns data user's duties regarding analysis outcomes derived from secondary use of data. Data user must publish the results of secondary use of health data within 18 months of the completion of the data processing in a secure processing environment or of receiving the requested health data. The results should be provided in an anonymous format. The data user must inform the health data access body of the results. In addition, the data user must mention in the output that the results have been obtained by using data in the framework of the EHDS.

12 Appendix 2: Methodology

The contributors participated according to their promised commitments, ensuring a collaborative and thorough development process. See below the information about our structured work together.

- Working meetings
  - We conducted four working meetings to discuss and outline the key components and structure of the guideline, as well as address any unclarities in the regulation.
- Write-a-thons
  - Five write-a-thons, each lasting three hours, were held to collaboratively draft and refine the content. What was not written during the write-a-thon was finished offline by the contributor who was given the responsibility for it.
- Consultations with DG SANTE
  - Three meetings with a representative from DG SANTE were organised to ensure alignment with regulatory requirements and to gather expert feedback.

We still expect the continued involvement of both minor and major contributors after the public consultation to implement the feedback received.