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Common data access application form

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2. Executive summary

The European Health Data Space aims to unleash the full potential of health data. HealthData@EU Pilot project is dedicated to developing and testing common European ecosystem and infrastructure to enable the cross-border secondary use of electronic health data. This report focuses on the project's Task 7.2, which is about developing a common European data access application form leaving some leeway for national differences.

As electronic health data can be used on statistical level and personal level, two different common application forms were developed: one for anonymous aggregated data and another one for anonymous or pseudonymised personal-level data. The form for requesting anonymous data is called a data request. Data users can utilise the aggregated data freely without specific security measures. The form for applying for anonymous or pseudonymised personal-level data is called a data access application. Ethical approval is often necessary for accessing personal-level data. Additionally, data analysis of such data can only be conducted in a secure processing environment.

The development of these forms was based on the European Health Data Space Regulation proposal published on 3 May 2022. Besides the Regulation proposal, primary sources were the existing data access application forms in some of the European Union member states, good national practices for granting access to electronic health data, as well as opinions and experiences from experts in research, application form processing and legal matters. Views, ideas and expertise were shared through several commenting rounds, workshops, project partner meetings and bilateral discussions.

The goal of the development process was to create application forms that cover all the essential elements for assessing whether data can be granted to applicants while being practical and not too burdensome to fill in or process. Furthermore, the forms had to be based on the EHDS Regulation proposal, be in line with the General Data Protection Regulation, and be as structured as possible to facilitate the automation of processing and translating the applications.

The deliverables of this Task are the two application forms and this report providing a broad view on the current state and practices of secondary use of electronic health data in project partner countries, and a variety of technical and general recommendations for implementing the data access application part of the European Health Data Space.

3. Context

This report presents a common European data access application form and a data request form developed as part of the HealthData@EU Pilot Work Package (WP) 7, Task 7.2. The Deliverables of this Task are the two forms in Word and Excel format and this report providing ample background information and recommendations. The work for this Task was conducted between February and December 2023 and it was led by the Finnish Social and Health Data Permit Authority Findata.

The instruction for the Task was the following: "Develop a common data access application form leaving some leeway for nodes' differences". The EHDS Regulation proposal establishes data access applications (Article 45), which refer to applications to access personal-level electronic health data in an anonymised format (Art. 45(2c)) or in a pseudonymised format if sufficient arguments are provided (Art. 45(2d)). Anonymised data in statistical format is provided via data requests (Art. 47(1)). As the requirements for the application form questions are somewhat different when seeking personal-level data and statistical data, two separate application forms were developed in this Task. The idea is that both forms are available on the same platform.

The objective of the application forms is to collect all the necessary information from applicants in order to assess whether they can be granted access to data. At the same time, the application forms must not be too burdensome for applicants to fill in or for the health data access bodies to process. Furthermore, the forms must be based on the EHDS Regulation proposal requirements for data access application form and data request, comply with the General Data Protection Regulation, and in case of EU bodies/agencies as applicants, comply with the EU Data Protection Regulation. It was also decided that the application forms should be made as structured as possible to enable partial automation of processing and ensure better translatability. As the technical implementation of the forms belong to the Task 7.3, this Task was limited to describing the envisioned technical features of the forms and providing recommendations to support the technical implementation.

The planning and creation process of the forms was based on the Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space [hereinafter: EHDS regulation proposal], given in Strasbourg on 3 May 2022. The proposal has been under negotiation for the whole duration of this Task and is subject to changes because of the on-going legislative process. As the final version of the Regulation remains unknown and the negotiations are envisaged to conclude only after the end of this Task, it was agreed that the development work would follow the original Regulation proposal.

Besides the EHDS Regulation proposal, the following documents were consulted: the Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (27 April 2016) [hereinafter: GDPR regulation] and the Regulation on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data (23 October 2018) [hereinafter: EU DPR], which are referred to in the EHDS regulation proposal. The data access applications from Denmark, Finland, France and Norway were used as a basis in the development of the common European data access application form and data request form, as those countries have a) a national system in place for applying for health data, and b) forms that are several pages long covering relevant information in a somewhat detailed way. In Belgium, research projects that make use of health data generally need an approval from the Information Security Committee. The form required by this committee was also considered.

Croatia has a general form for accessing information, but it is not comparable with the Danish, Finnish, French or Norwegian ones due to its shortness and very narrow scope of questions. It was therefore not further considered in this Task.

The following materials were also consulted in the development of the common data access application: Findata's Regulation on data content and data structures of data permit applications and data utilisation plans, the list of data fields used in the One Million Genomes project, and the materials from the European Commission DG SANTE Analysis and design of the European Health Data Space infrastructure for secondary use of health data (HealthData@EU) (14 March 2022).

According to the original plan, the teams involved in use cases (Work Package 9) were to test the data access application form and provide input for this Task. However, due to a change in their plans, they were involved in this work by participating in workshops that were organised as part of this Task. The Work Package 9 use cases will report on the application processes in all nodes, which will illustrate the difficulties in accessing data. Once the application form is approved, the use cases will test it.

A mapping and analysis of secondary use of health data and data access applications in several Member States was conducted in HealthData@EU Pilot Work Package 7 as Task 7.1. This exercise, called Landscape Analysis, provided information on the already existing data access practices and application forms in different countries. The information gained from this Landscape Analysis was considered in the development of the common data access application form.

The Landscape Analysis materials illustrated the diversity in the quantity and quality of available health data and practices of the secondary health data among the participant countries. No country has stored all of its health data in one place. Some countries have cancer, vaccination and/or death records, and some collect and combine social data, such as unemployment or pension statistics, with health data. The different practices and starting points for secondary use of health data were among the main challenges in the development of the common application form.

The model for data access application proposed in this Task is a one-step process, meaning that all information needed for reviewing the application is gathered at once. This is similar to the application processes in most of the Member States that participated in the Landscape Analysis. As transferring, sharing and managing health data across the countries within the European Health Data Space will require a rather complex system, opting for a one-step process contributes to a procedure that is as simple as possible from both the applicants' and the health data access bodies (HDABs) perspective.

Depending on the case, applicants usually need to attach one or more documents to the application. Such attachment is e.g. a review by an ethics committee. The requirements in each country vary and the application form needs to be flexible and leave space for national differences in this regard.

4. Methodology

The starting point in the development of the common application form was mapping the elements of the application process from the beginning to the end. The European Commission document presenting the end-to-end user journey of the European Health Data Space

infrastructure (14 March 2022), the European Health Data Space Regulation proposal (2022), as well as several national data access applications were reviewed to identify the necessary elements in the application form.

As a result, the application form would consist at least of the following parts:

1) General information about the data access application and the fees for both processing the application and the possible costs of data retrieval and delivery
2) Purpose of data use
3) Defining the necessary dataset(s)
4) Indicating any plans to combine other data with the data applied for
5) Data processing plan

Each of these sections consists of sub-sections and more specific questions.

Even though the data access application and data request have different requirements, they also share several same sections. Overall, the data access application form is longer. The development work focused first on the data access application form, and once it was nearly ready, the Task leader created the data request form. That is why this report refers often to only data access application form.

It was important to clearly identify which parts in the whole data access application process would fall within the scope of the application form and this Task 7.2, and which actions are taken before or after filling in the form. Before filling in the form, applicants can browse the EHDS metadata catalogue to check if the data they need are available. They also need to acquire any necessary documents, such as a positive ethical statement for the planned data use, depending on the country of origin of the data, and the purpose of data use. Then they can proceed to filling in the form. After submitting the form, an HDAB processes it. If a data permit is granted, the HDAB prepares and provides the data.

The next step was studying the application forms of those project partner countries that have one to see what is asked in them. An Excel sheet compiling all the questions was created. These questions were analysed in terms of their usefulness with regards to the process of applying for data within the EHDS.

The first draft of the application form was created in a Word document to enable easy editing while making it look somewhat similar to an actual form. In addition, an Excel version of the draft application form was created to have the questions in a list and columns to show the question type (e.g. checkbox or free text field) and if they feature in the forms due to the EHDS, the GDPR or operational reasons. The category of operational reasons refers to practical information that is essential for application processing, such as contact or invoicing information. Later in the process, a new Excel of the application form was created, this time listing and grouping the questions according to the EHDS Regulation proposal articles related to the two forms.

4.1 Comparing the already existing application forms

The Task 7.1 Landscape Analysis shows that some kind of a data access application form exists in the following countries participating in the WP7: Belgium, Denmark, Finland, France and Norway. The organisations providing these forms in each respective country are the Belgian Information Security Committee, the Danish Health Data Authority (DHDA), the Finnish Social

and Health Data Permit Authority (Findata), the French Health Data Hub (HDH) and the Norwegian Directorate of e-Health (Direktoratet for eHelse).

The application forms are not completely comparable because some of them enable applying for all sorts of health data while others are organisations' own forms covering a limited number of data sources and uses. Finland and Norway have a separate application form for anonymous aggregated data and pseudonymised personal data. The Finnish application form for pseudonymised personal-level data is called a *data permit application,* and the form for requesting anonymous aggregated data is called a *data request application.* Denmark has two application forms for applying for data in DHDA's national registers: One is used when applicants seek to process data inside an environment called "Research Machine" (Forskermachine), and the other is used when they want to process the data in another secure processing environment.

In Denmark, researchers need to first present their research proposal to a data controlling authority and/or an ethics committee for a review and can contact only afterwards the national health data authority, if given green light.

In Finland, applicants need to first make sure the necessary data are available by using the national metadata catalogue and contacting the data holders. If they apply for pseudonymised data, two attachments are mandatory in the application form: a document indicating which data are to be retrieved and a privacy notice regarding the requested data, i.e. a document informing the data subjects of how their data are used as per the GDPR. Moreover, depending on the type of the study, they might need to attach some of the following documents: research plan; research permit from the organisation responsible for the study; positive ethical statement; a description of the sampling method of the study cohort; study cohorts' consent form template; previous permits concerning the study cohort and their relatives and controls, or other materials to be linked with the requested data; and Data Protection Impact Assessment, when required by the GDPR or the Data Protection Act.

When requesting anonymised data, applicants need to attach a document indicating which data are to be retrieved, a tabulation plan, which is used by Findata to create the requested statistics and a research plan (if data are used for research). In some cases, they might need to attach a research permit from the organisation responsible for the study and a positive ethical statement.

In France, the application process consists of submitting the plan for data use to the ethics committee, and once an approval is obtained, submitting the data access application to the National Commission for Computing and Liberties (CNIL) for authorisation. In certain cases, authorisation from CNIL is not necessary.

The French HDH provides preparatory documents for applicants to help them fill in the actual application documents. The checklist for items to be covered by the research protocol are to some extent similar to the questions asked in the Finnish data permit application form. Besides the preparatory documents, HDH offers applicants instructions and information in French on its website. Findata provides extensive instructions and information in Finnish, Swedish and English on its website. Additionally, some instructions are also integrated in the application form itself as text between questions and pop-up windows when the user hovers over a question. Findata also organises regular "application clinics" that are open to anyone.

In terms of application form structure, the French form relies on open text fields, while the Finnish forms have more structured answer fields, making use of dropdown menus, radio

buttons, and others, on top of open text fields.

The Finnish application form specifically asks whether the research using the requested data is for a thesis, and in such case the names of the author and the supervisor are needed. This question is relevant because in Finland students pay lower fees for data compared to other applicants. The same question does not feature in the application form of any other country.

When it comes to the study cohort, the Belgian, the Finnish and the French application forms require applicants to fill in detailed information regarding the study cohort, such as its size, and the "extraction method". In addition, applicants need to include a description on how the target group shall be formed. The Norwegian application provides a free text field for describing the study cohort (called 'study population' in the form) without any specifying questions. The Danish form features many attachments, including project description and extraction description and does not ask questions related to these attachments directly in the form.

The questions regarding secure processing environments are also different. The Finnish form offers an option to use the operating environment managed by Findata, or alternatively applicants can choose another environment and provide an explanation why it would be preferred. The Norwegian form does not cover the operating environment, but the Norwegian health data access authority asks details on the data analysis environment to be used. Denmark has one application form for those who plan to use the Research Machine secure processing environment and another one for those opting for another secure processing environment.

4.1.1 Role of ethical reviews

In terms of ethical approvals, practices among countries vary. Belgium requires applicants to acquire an ethical review before filling in the data access application. In Germany, ethical review is mandatory, but even in case of not receiving an approval, the person can proceed with the application for data. When it comes to personal identifiable data, submitting a research proposal for a review by an ethics committee is necessary in most of the countries. In cases of purely register-based research, an ethical review is not needed in Finland, and thus, the Finnish authority, Findata, does not request for an ethical review. However, according to the national laws, an ethical approval is needed when applying for health data for certain kind of research purposes. Norway asks for an ethical approval when personal identifiable data are used for health and medical research purposes, i.e. in the large majority of the cases. Ethics committee does not need to be consulted when using health data for other purposes, such as for other research purposes or for governmental and decision-making purposes. Croatia requires an ethical approval except for cases in which electronic health data are in aggregated form with cell sizes big enough.

4.2 Exchanges with other Work Packages and Tasks

Regular meetings with the project coordinator and Work Package leader were held to discuss the progress of the data access application form development and share ideas for it. Task 7.2 progress was presented in monthly Work Package 7 meetings. Some coordination meetings between Task 7.2 and 7.3 (providing specifications for central data access request portal) were held to discuss the technical questions related to the forms. Furthermore, occasional meetings with other WPs were organised to ensure seamless coordination between them in the HealthData@EU pilot project.

4.3 Commenting rounds

The first draft of the application form was finished in June 2023 and sent for comments in early July. About eight project partners provided their comments which were considered and integrated as applicable in the form. The application form including these new additions and modifications consisted of the second draft version of the Deliverable. The commenting round for the second draft was done in a workshop format at the end of August. It was the main workshop of this Task (more information on it in the next sub-chapter). The results of the workshop discussions were integrated in the form and the new version constituted the third draft of the application form. The Task leader and the project coordinator jointly assessed the third draft version of the form as a whole and some minor edits were made.

The version that was sent to the final consortium comment round at the end of November was the fourth draft. Consortium members and the External Advisory Board had the chance to comment in early December. The European Commission DG SANTE unit C1 also provided their comments during the final comment round.

After that, the final editions were done and the fifth version, i.e. the finished Deliverable, was sent to the European Commission/HaDEA before the holiday season in December 2023.

Besides these official commenting rounds and opportunities, the Task leader has throughout the project encouraged project partners to provide any comments they might have on the application form at any time and in the manner suitable to them.

4.4 Workshops

On 29 August 2023, a three-hour online workshop was organised by Findata to discuss the application form, share ideas and address the most challenging parts of the application form. The workshop hosted 38 attendees, with at least one representative from nearly every organisation participating in the Task 7.2, and some external experts invited by these organisations. The participants encompassed a wide range of relevant expertise, including data users, people processing data access applications and legal officers.

The workshop programme consisted of presentations, questions to speakers, discussions on various sections of the application form and sharing views, experiences and ideas. Among the speakers were an expert from Findata who explained the Finnish data access application process and the key challenges, and an expert from the French Health Data Hub who presented the French data access application process. A representative from the European Commission spoke about the legal requirements for the application form in the EHDS Regulation proposal.

Among the topics discussed were the data utilisation/research plan and their form, contents and requirements. It was also discussed whether applicants need to have a certain level of education in order to apply for electronic health data, but it was decided that no such requirement will be added in the application form. When talking about the Data Protection Impact Assessment, it was discussed who is responsible for conducting it and whether it should be required as an attachment in the form. Towards the end, it was discussed whether the data extraction description should be an attachment or not. If, at some point, applicants will need to provide variable-level information on the data they seek, a separate document outlining the extraction criteria should be used and added to the application form as an attachment.

Finally, it was clarified that the EHDS Regulation proposal indeed aims for two types of application forms: one for individual level data, either pseudonymised or anonymised, and

another one for aggregated data. Even though many questions were left for further discussion and new questions were raised, overall, the workshop served as a platform for open discussion on various topics and was an important part of the application form development.

The event received overall positive feedback from the project leader and several other participants who shared their comments via e-mail or during the project meetings following the workshop. The project coordinator and the European Commission wished for further analysis of and discussions on the still open subjects in the form. Moreover, they wished the Task leader to structure the questions according to the relevant articles in the EHDS Regulation proposal and further consider the role of the ethical review in the application process. It was therefore decided to postpone the original deadline (end of September 2023) to the end of December 2023.

A series of short online workshops, each lasting an hour, between 21 September and 26 October were held to discuss the open topics. The first workshop focused on data utilisation/research plan and data format (pseudonymised/anonymised). The second one dealt with data extraction description related questions. The third workshop was about data protection and safeguards, lawfulness of processing and data processing questions. The fourth one covered questions related to public information about the project, data processing environment, ethical review and scientific criteria for research. The fifth session was organised in person during the HealthData@EU pilot General Assembly in Paris, and it focused again on questions related to purpose of data use and data utilisation/research plan. Operational questions, e.g. applicant and contact person information, as well as fees, were covered during the last mini workshop session.

5. Data access application form and data request

Despite being separate application forms, data request and data permit application could be filled in in the same portal. The portal could be provided by the European Commission's Central System, which would distribute the applications to the HDABs in question.

The portal could work in the following way: First, applicants go through a general section consisting of a glossary of the key terms of data access application process, general information on data access applications, information on fees and an explanation of the differences between a data request and a data permit. Based on the data needs, applicants indicate which application they want to fill in, and the corresponding form opens.

5.1 Data access application form

The Proposal on the European Health Data Space states that the data access application shall include (Art. 45(2)):
(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;

(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States;

(c) an indication whether electronic health data should be made available in an anonymised format;

(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;

(e) a description of the safeguards planned to prevent any other use of the electronic health data;

(f) a description of the safeguards planned to protect the rights and interests of the data holder and of the natural persons concerned;

(g) an estimation of the period during which the electronic health data is needed for processing;

(h) a description of the tools and computing resources needed for a secure environment.

5.1.1 Selecting the health data access body

At the beginning of the application form, applicants select the health data access body to which they want to address their application. The selection of the HDAB is made based on the country of origin of the requested data. If, for example, an applicant wants data from Spain and Italy, they can choose an HDAB in one of those countries.

5.1.2 Public information on the project

EHDS legislation requires the HDABs to publish:

- Art. 37(1q, iii): *"all data permits, requests and applications on their websites within 30 working days after issuance of the data permit or reply to a data request"*
- Art. 37(1q, iv): *"results communicated by data users pursuant to Article 46(11)"*, i.e. results or output of the secondary use of electronic health data.

Currently, the authorities responsible for granting permits for secondary use of electronic health data in EU Member States have diverse practices regarding the information disclosed on their websites in relations to data permits. Before deciding which information in the EHDS application form should be published, a comparison between the public information on the websites of Health Data Hub and Findata was done. The French authority publishes more information than the Finnish one, but applicants are not obliged to provide answers to all questions asked by the HDH.

If applicants answered to all of the questions posed by HDH, the following information would be published: study objective, medical field, data categories used, anticipated benefits of the project, methodology used, origin of data, population concerned, type of data controller, data controller, data protection officer, representative of the data controller, implementation manager different from data controller, timeline and progress status of the project, data recipients, duration of data processing, regulatory framework, existence of automated decision-making, information on the legal basis of the project and transfer of the data outside the EU, any sensitive variables used and information on how the rights of individuals, whose data are being used, are addressed.

Findata publishes the start and end dates of data permits, the name of the organisation and study group conducting the project, data use purpose, as well as a one-paragraph summary of the project. The Finnish Act on the Openness of Government Activities restricts the amount of information that can be disclosed.

It was decided to limit the public information gathered from the EHDS data access applications to the minimum that would comply with the requirement to publish "all data permits, requests and applications" (Art. 37(1q, iii). The HDABs would therefore publish the following information: project name, project leader name and country, data use purpose, description of the data to be used and summary of the project. Ideally, applicants would provide answers to all of these

questions, but in some cases, due to the nature of the projects, it might not be possible for them to disclose all of that information to the public. Examples of this kind of case with a limited amount of information to the public could be data users planning to apply for a patent or a pharmaceutical company that cannot comply with full transparency due to competition. This issue is taken into account, and applicants are given an opportunity to explain why certain parts of their answers cannot be disclosed. Additionally, two optional questions related to research objectives and area of research are asked.

If a data permit is granted, the HDAB shall also publish the start and end dates of the permit on its website. However, this information does not come from the application form but is based on the information in the data permit.

In addition, the form reminds applicants of their obligation to publish the results or output of their secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the processing of such data or after having received the answer to their data request (Art. 46(11)). Article 39(1m) also requires the HDABs to provide the "number of peer-reviewed research publications, policy documents, regulatory procedures using data accessed via the EHDS", which is also mentioned in the application form.

5.1.3 Applicant and contact person information, payment details

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.

During one of the workshop sessions, it was discussed whether to ask applicants to provide the name of their employer and the contact person's employer. The outcome of this discussion was that such information is unnecessary for the application processors to know and asking it in vain could even constitute a breach of privacy.

In the draft versions of the form applicants were asked whether they have sufficient funding for the project and who or which organisation provides it. The idea of these questions was to make sure that the project would be financially covered so that the HDAB would not need to process any applications in vain. Knowing who the sponsor is, however, is not relevant regarding the decision on whether to grant data access. It was first decided that a general "Do you have funding for your project?" question is enough. However, as it is currently not possible for applicants to know the final price of the requested data, it was concluded that no question regarding funding is relevant. However, it is necessary to ensure applicants are clearly informed that submitting an application and accessing data have a cost. That is why the general section in the application portal includes information on fees, and at the end of both data access application and data request forms applicants need to check boxes confirming they have understood that fees will apply for processing the application and if data are granted, HDAB and data holder(s) may charge a fee for providing the data.

5.1.4 Purpose of data use

Applicants should indicate the purpose for which data are sought. According to the EHDS Regulation proposal Article 34(1), the proposed valid purposes for secondary use of electronic health data are:

a) *activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices*
b) *to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates*
c) *to produce national, multi-national and Union level official statistics related to health or care sectors*
d) *education or teaching activities in health or care sectors*
e) *scientific research related to health or care sectors*
f) *development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices*
g) *training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices*
h) *providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.*

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.

The requirements for the data utilisation plan or research plan and their possible integration in the application form questions were discussed during several workshop sessions. Opinions were divided among the workshop participants: some thought it should be included in the application form as an attachment, others preferred not having it as an attachment but covering its essential elements by the application form questions. A hybrid model was also brought in: applicants would attach their plan in the application form and the form would include a checklist of key questions related to the research plan. Applicants would respond by indicating the page number in their plan where each question is addressed.

Reading through the entire data utilisation/research plan was deemed to be time-consuming and burdensome for the HDAB processing the application form. Consequently, the decision was made to incorporate all essential elements into the application form as questions. These elements were identified by compiling a list of the most common requirements for research plans and analysing which are important regarding the HDABs decision-making.

Under the purpose of use section, applicants need to indicate whether they are applying for pseudonymised or anonymised personal-level data. The need for pseudonymised data must be justified.

5.1.5 Defining the dataset needed

In this section, applicants define the criteria for data extraction which will enable collecting the

requested data from the data holder(s). Applicants should apply only for the necessary volume of personal data, following the principle of data minimisation of the General Data Protection Regulation. If applicants have been in contact with someone in the HDAB regarding the data they would like to get, they can list the names of these persons in this section. This information helps the HDAB if they want to assign the application for a processor already familiar with the requested datasets.

First, applicants indicate how the study cohort is formed. They can define the criteria for a new study cohort or use an already existing one. It is also possible to combine an old study cohort with a new one. Applicants choose from dropdown menus the country/countries and the more specific geographical region (if applicable) from which data are sought. Then, they select the data holder(s), database(s)/registry/registries. Due to the vast number off databases, only the biggest ones will be included in the dropdown list. Applicants have the option to select 'other' and manually enter the name of their desired database if it is not featured in the list.

The application form displays to applicants whether an ethical review is required, based on their selected country. Additionally, depending on the choice of country and data holder, other necessary attachments will be identified and shown after these selections are made.

When defining the dataset needed, applicants should aim to provide answers to the following questions:

- Whose data will be extracted? What are the inclusion and potential exclusion criteria?
- Are controls to be extracted for the study cohort? If yes, applicants must provide specifications.
- Will data concerning the study cohort members' relatives be extracted?
- In which order and over which period of time will the data be extracted? If the extraction takes place in multiple steps, applicants should specify the order in which the requested data will be extracted.
- Will any other data be combined with the data applied for?

If data are sought from several countries, the dataset needed should be described separately for each country. For example, if an applicant wants data from two countries, the extraction criteria section should appear twice, as the applicant may want different data from each country. Even if the applicant wants the same data from both countries, most likely the same criteria do not yield the same results due to national differences in data collection and variables.

Extracting relatives for a study cohort is a very common set-up in epidemiological research. The availability of such control group data is likely to vary from one country to another. This aspect requires therefore further discussion.

In case applicants plan to combine the requested data with other data from outside of the European Health Data Space, such as previously collected survey data or other register-based data not related to health, these other datasets should be listed in the data permit application. Any pending permit application being processed by other authorities should be mentioned as well. All this information is necessary for the HDAB to gain a comprehensive understanding of all the data that will be linked. It enables them to consider the data protection aspects and assess the risk of data subjects' identification.

The term 'study cohort' was chosen to refer to the group of data subjects whose data are

studied. The term may not be optimal due to its association to research, as secondary use enables other use purposes as well. Other options considered were 'study population', 'data subject group', 'target group', and 'data population', but study cohort was chosen because it was regarded as the most established one.

5.1.6 Data processing, data protection and safeguards to prevent unauthorised use of data

In this section, applicants provide information on the technical requirements for the secure processing environment, data protection and safeguards to prevent any other than the planned use of the electronic health data. Moreover, applicants need to specify when they need the data. Usually, the HDAB processes applications in the order of their arrival. In case applicants need the data later than as soon as possible after the normal processing order, they can indicate it in this section. In addition, applicants provide the estimated start and end dates of their data processing.

Applicants are asked whether the data will be transferred outside the EU or the European Economic Area (EEA). The info button of this question explains the three cumulative criteria to qualify a data processing operation as a transfer, identified by the European Data Protection Board (EDPB). Given the complexity of the topics of data transfer, which is covered in detail in the multi-page guidelines issued by the EDPB, the application form does not offer an exhaustive explanation of the topic. Instead, it provides a link for further information on the topic in the info button.

If the data will be transferred outside the EU/EEA, applicants are asked about the legal basis for transferring the data. If transfer is done based on appropriate safeguards provided by the data controller or processor, applicants need to select the way in which these safeguards are provided. Initially, it was suggested that the final answer option for this question would be "Provide here a link to the instrument/binding corporate rules/code of conduct/certification mechanism". However, evaluating whether the documents are valid and sufficient is not part of HDABs' mandate but Data Protection Officer's responsibility.

Applicants are also asked which organisation or individual will be the controller of the data. Usually, the controller will be the applicant using the data. Nevertheless, this kind of clarifying question is useful when a person is applying data on behalf of someone else who will be the data user. In addition, in cases of joint controllership, the applicant can provide the names of the controllers.

5.1.7 Data protection and safeguards to prevent misuse

This section addresses controllership of the data, compliance with the principle of data minimisation of the GDPR and general safeguards to prevent any other use of the electronic health data than the one indicated in the application form.

Applicants need to list the people who will be processing the data. This may become an issue, as there may be a need for changing the data processors during the project. In these cases, Findata requires the data user to submit an amendment application. However, a new application incurs additional costs and increases the bureaucratic workload in the overall process of data use. In Norway, each project has one assigned project manager who is granted the data and the responsibility to ensure that the data are used according to the permit. Additionally, the project manager is responsible for keeping an updated list of all the people who need access to

data.

In this section, applicants need to confirm the lawfulness of their data processing according to the GDPR Article 6(1). If the application is filled in by a representative of an EU body, institution or agency, Article 5(1) of the EU DPR on lawfulness of processing will appear. Furthermore, applicants can attach a Data Protection Impact Assessment and a research permit from the responsible organisation, if applicable.

5.1.8 Additional information and confirmation of the information provided

Towards the end of the application form, applicants are given a space for providing any other relevant information that may not have been covered by the previous questions. The application has also space for an additional attachment, should applicants deem it necessary to provide one. Applicants are instructed to describe the relevance of the attachment and the section to which it refers in the above field for 'additional information'.

At the end of the form, applicants are required to confirm they understand the policy regarding fees and that the information they have provided is correct.

5.1.9 Submitting data permit application forms

Data permit applications are submitted to the EHDS Central Services. Based on the information provided in the application, the HDAB processing the application assesses whether the requested data are necessary and appropriate for the described purpose(s).

Data access applications and their attachments are confidential.

5.2 Data request form

Data request is used when applicants seek statistical, anonymous data formed from personal data by the HDAB.

According to the EHDS Regulation proposal Article 47, a data request application form should at least include the following elements:

a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;

b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States.

If needed, it can also include a description of the expected result from the health data access body and a description of the statistic's content (Article 47, EHDS Regulation proposal).

All the remarks made in the data access application section apply in the data request form regarding the common questions between the two application forms. However, some differences between the data access application and the data request exist.

One essential difference relates to data processing safeguards: the whole section on *Data processing, data protection and safeguards to prevent unauthorised use of data* is not featured in data request. Anonymised aggregated data does not need to be processed in a secure processing environment.

In the *Description of the dataset needed* section applicants are asked to provide a tabulation

plan for each statistic that they request. The tabulation plan serves as a model for the HDAB on how to compile the statistics. The model should not contain any health data when attached to the application.

6. Other remarks on the application forms

This chapter explains important issues in relation to the data access application form, data request, or both.

6.1 Ethical review

The article 45 of the EHDS Regulation proposal states that when applicants seek to access personal electronic health data in a pseudonymised format, "information on the assessment of ethical aspects of the processing, where applicable and in line with national law" should be provided. The common data access application form shows whether an ethical review is needed based on the applicants' answers.

During the development process of this form, it was suggested that the ethical review questions should be integrated in the form. This proved to be difficult due to various reasons. First, numerous ethics committees exist in the European Union – there can be several even within one country – and it would be very complicated and time-consuming to compile a comprehensive list of questions considered by each committee. Second, harmonising ethical reviews has been discussed for several years without success. In the current system, it is not guaranteed that a positive ethical statement given in one country would be accepted in another. If harmonisation of ethical reviews and statements is the goal, international standards should be created. Third, linguistic barriers could prove to be an issue if there is no automated translation system for the statements. It was therefore concluded that, in the current framework, integrating ethical review in this form is not possible and the work it would entail falls beyond the scope of this Task.

However, an initial mapping of the issues evaluated by ethics committees was done. The project coordinator, Health Data Hub, shared a list of questions asked by their scientific and ethics committee, CESREES. The task leader, Findata, gathered information on the topics assessed by the Finnish National Board on Research Integrity (TENK). The materials are however not directly comparable with each other, as the Finnish ethics committee evaluates the research based on wider topics and does not have a list of specific questions like the French one. The mapping exercise was also very narrow in scope, as other Task participants did not provide information on their ethics committees.

The French ethics committee assesses questions related to the following categories: purpose of data use, research context and objective(s), justification(s) of the project and its ethics, plan for publishing the results, method and analysis, description and justification of the chosen study population, data processing, international transfer of data and data recipient(s). Most of the questions assessed by the French ethics committee were already included in the draft of the common data access application form. The questions not covered by the form are for example scientific context of the study and benefits of the research for society.

In its ethical review, the Finnish board focuses particularly on:

- the possible risks and harms for the data subjects, their relatives and the researcher themselves and the probability of those risks

- informing the data subjects on the study and processing of their personal data
- data management plan and processing of personal data during the life cycle of the study
- the appropriateness of the consent given by the data subjects
- the way in which consent was requested and documented
- the significance of the new information the research would produce in relation to the potential harms

The ethical principles of TENK are in line with The European Code of Conduct for Research Integrity by All European Academies (Allea).

6.2 Data Protection Impact Assessment

The EHDS Regulation proposal does not mention Data Protection Impact Assessment (DPIA), but according to the GDPR Art. 35(1), a DPIA should be conducted

> *"Where a type of processing in particular using new technologies, and taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall, prior to the processing, carry out an assessment of the impact of the envisaged processing operations on the protection of personal data."*

A DPIA is required by law when, for example, health data and/or children's data are processed. A DPIA needs to be done before the beginning any data processing activity and during the different stages of the project.

The issue of DPIA was discussed several times during the workshop sessions and legal experts gave their views on whether it is relevant and necessary to ask applicants to provide a DPIA as part of the application process to apply for pseudonymised electronic health data. Some argued that it is necessary for applicants to do so, while others said that, as the data are processed in a secure processing environment, data users do not need to provide a DPIA. The secure processing environments have built-in safeguards to ensure data protection. It was also suggested that the HDAB should do the DPIA because it knows the secure processing environment (SPE) and its limitations. This may not be entirely true, as there may be several SPEs within one country, and the HDAB may not know all their features at a very detailed level. Another argument was that as the HDAB links the different data, it is better equipped to assess the risks. To conclude, the DPIA question was left out from the data access application form.

6.3 Main challenges in the development of the forms

One of the challenges in this Task was the fragmented landscape of electronic health data available for secondary use. The quantity and quality of such data varies significantly from one Member State to another, and so do the means and practices for linking these data. Besides, the classification of data is diverse: concepts such as 'dataset' or 'registry' can be understood differently in different countries.

The EHDS metadata catalogue is being planned to operate at dataset-level. Therefore, the questions related to variables in the common data access application and data request form are marked as optional. Having no variable-level metadata available poses some challenges. For applicants, this means not having detailed knowledge about the contents of the data holders' databases. For HDABs, complying with the GDPR's data minimisation principle will be a challenge, because it is harder to pinpoint applicants' exact data needs when the discussion is

based only on dataset-level information. Moreover, the data requests from the HDAB to the data holder will be defined on the dataset-level, not detailing which variables to include or exclude. When it is the HDAB who does the actual data processing rather than the applicant – which is the case with aggregated data requests – it will be necessary to find a way for applicants to be able to give detailed instructions to the HDAB of the needed information content.

A wider set of countries sharing information on their data access applications and processes would have given a chance to develop a broader overview of the current state of data application processes in the EU countries. Additionally, the EHDS Regulation proposal was limited in scope; it lists some basic requirements for data access applications, but it does not mention all the information needed in data access applications, such as contact person information or invoicing details. Moreover, the Regulation proposal does not go into detail in terms of data extraction related questions that are required. Therefore, it was very valuable to receive inputs from project partners that have experience in processing data access applications.

A fundamental question throughout the process was related to the format of the form questions: opting for questions with open text answer fields or structured answer options, such as dropdown menus or radio buttons. On one hand, free text fields allow applicants to provide information more freely and may better suit various user needs. However, they also increase HDABs' workload, as each response required individual reading and processing by a human. On the other hand, structured answers are easily machine readable and translatable, making the processing faster, but they significantly limit the responses, which may cause problems or require more correspondence with applicants, resulting in longer processing times.

Based on these reflections and many discussions, it was decided to opt for structured answer fields wherever possible. In cases where structured answer options would hinder the flow of information from applicants to HDABs, a free text field was chosen. For now, most responses are to be given in a free text format.

The diversity of accepted use purposes for the secondary use of electronic health data has been considered throughout the development of the form. The form has been built to be as comprehensive as possible, aiming to minimise the need for HDABs to contact applicants during the application processing. The 'any further information' text field by the end of the form is intended to be a space where applicants can provide further explanations for any of their earlier responses or share information that did not fit in any of the other answer fields. Despite the possibility to provide additional information and insert an additional attachment, as well as the overall versatility of the form, applicants or HDABs may still need to contact the other one for further questions or clarifications.

When it comes to public sector or EU bodies applying for data, further clarifications are needed. The derogations from the Regulation that apply to these applicants are somewhat addressed in the application form, but open questions remain in the original proposal. It is necessary to discuss to which extent HDABs are expected to check and verify the legal basis which define the tasks falling within their mandate and if those are in line with the indicated purpose of data use. Furthermore, according to the Regulation proposal, public sector bodies or EU bodies do not require a data permit to access electronic health data. It is not clear whether these applicants go through the same process (besides the specific derogations) when applying for data, or if separate tracks will be established.

7. Recommendations

In this section, the Task leader provides recommendations that have emerged along the development process or stem from practical experience on processing applications. Technical recommendations are related to the possible portal where the applications will be available. Other recommendations are any other ideas to consider.

7.1 Technical recommendations

To make the application process as smooth as possible, relevant fields could appear and irrelevant ones disappear based on the applicants' answers and selections. For example, if they indicate that data are needed for research purposes, questions related to research appear. Similarly, the form leaves leeway for national differences: it provides information on specific national regulations and the necessary country-specific attachments based on the country selection(s) applicants make.

The application form should also make use of fields with fixed options, such as dropdown menus, and questions with multiple-choice answer options, such as checkboxes and radio buttons, as much as possible. The number of open text fields should be the lowest possible. An application form that is designed this way will allow the health data access body to obtain all the information needed in as simple and compact a manner as possible, which makes reviewing the application easier. It will also enable at least a partially automated processing of the application. Moreover, fixed fields and elements make translation of the form much easier.

There are several technical solutions for structuring the answer options in the form. Radio buttons are graphical elements that allow applicants to choose only one answer option from several choices. In contrast, checkboxes are graphical elements that allow choosing several options. A third type of graphical element planned for the form are dropdown menus. They allow presenting several options in a clear way. After clicking the arrow in a dropdown menu, a list of several options open, and the user can select one. In some cases, selecting more than one option is possible, and each selected option could be displayed next to the menu. Typically, a delete button is provided in the corner in case the user wants to remove a selected option. A good practice is to use radio buttons when there are two or three options, a dropdown menu with four or more options, and checkboxes when there are clauses to be read and confirmed. In cases where the answer options are long and only one option can be chosen, radio buttons are recommended.

Instructing applicants on how to correctly fill in the application form is essential to ensure health data access bodies receive all the necessary information and to reduce the times they need to get back to applicants. Instructions are given as regular text between questions, as well as through info buttons that could open a small built-in pop-up box when the user hovers their mouse over the button.

In the section describing the requested dataset, table-like text fields could be used. See below an example from Findata's data permit application form:

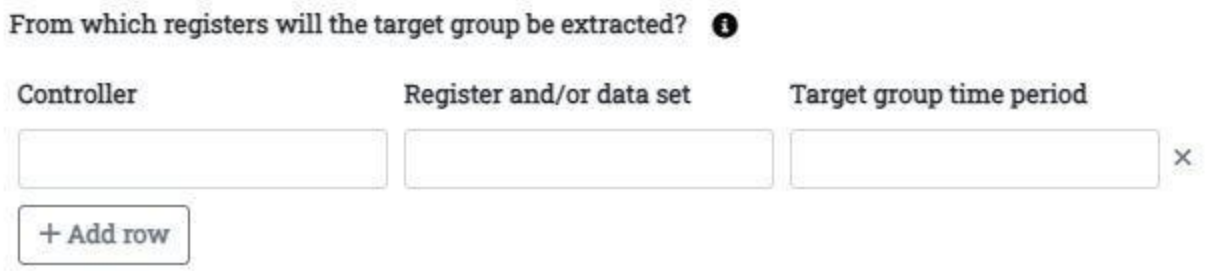

Figure 1: A screenshot of the extraction description section of Findata's data permit application.

Here, *controller* refers to the data holder and *target group* refers to the data subjects whose data are studied.

The common metadata catalogue could be linked to the application form in the section where applicants select the country/countries from which they want data. Based on the selection(s), a list of available data categories would appear, followed by the available datasets, and finally, the available variables, if, at some point, variable-level data is integrated in the catalogue.

The current plan for the common metadata catalogue is that it will only be on the level of datasets and will not allow detailed functions. If the catalogue is developed further in the future, it could be built to work in a click-and-collect style similar to online shops where the user adds items to an online shopping cart. This way the system shows whether the necessary data are available before applicants proceed with filling in the rest of the information.

As the form is rather long and complex, applicants will most likely not be able to fill it in at one go. That is why creating a portal where applicants can create an account and save a draft version of their application before submitting it should be considered. Once creating the account and/or when logging in, applicants could be authenticated via an electronic identification method.

The possibility to save the form as a draft, or having a system that automatically saves the work is important also because applicants may not be aware of all the required attachments beforehand or may need to edit the application information. This way they can obtain the necessary attachments and come back to complete the application. Frequent data users could benefit from a data applicant profile, which would save applicants' information and provide a partially pre-filled form the next time they apply for data.

Due to the length and complexity of the form, it is also essential to make the application platform as clear and user-friendly as possible. Each section of the application form could be divided under separate tabs. A user experience designer could go through the form to ensure a proper usability.

As per the Article 46(11) requirement for making public the results or output of their secondary used of electronic health data, the system could send an automatic reminder to applicants of this obligation well before the deadline of 18 months. The same could apply to approaching end date of their data permit – either the data will be deleted from the SPE or the permit holder will need to apply for an extension of the permit.

7.2 Other recommendations

When it comes to supporting applicants, HDABs and or the EHDS Central Services could offer applicants detailed instructions for filling in the data access application form. This could be done by publishing information on a webpage, creating brochures and videos, and even organising online application clinics to share information and answer applicants' questions. HDABs could also share general information related to secondary use of health data, relevant GDPR articles, and the roles and responsibilities of data users and data safeguarding measures.

The language aspect requires attention as well. The common data access application form is developed in English, but to ensure better functionality and smoother data access processes, the application form should be available in any of the 24 official EU languages, and applicants should be allowed to fill it in in any of these languages. This would of course require developing linguistic solutions and/or providing translation services for authorities processing the applications.

The data access application processing experts among the project partners that were consulted during the completion of this task raised the necessity for harmonising the data permit templates. They strongly recommend common templates for the data permits issued within the European Health Data Space. Differences in the permit structure and content complicate the processing of amendment permits.

When it comes to amendment permits, a common EHDS procedure is needed when applicants wish to make changes in a formerly granted data permit that remains valid. Amendment applications could be used to apply for an extension to the period of validity of the data permit, when the data processors are changed, or if it is necessary to change the period of data extraction, to cite a few examples. However, applying for a new permit has a cost and takes time. It may not be a feasible solution on the European level to require an amendment permit every time data processors in a project change.

During the development process, it was discussed whether it is necessary to know if the data will be used for a thesis or a dissertation. In Finland, the fees for applicants using the requested data for a thesis or a dissertation are lower than the regular fees. However, as the EHDS Regulation proposal does not mention anything similar, the question was not included in the common form. In case the same practice is spread across several EU countries, adding such a question is worth considering.

Public information of the project is to be published on HDABs' websites. Besides the public information covered by the application form, HDABs could also publish the status of each application, e.g. "being processed", "waiting for approval", "granted", or other. It is important to establish a system that caters the needs of citizens wishing to stay informed on which health data are granted for secondary use. They must be able to easily browse and sort the information. The data types and amounts could be illustrated with the help of diagrams, such as the circle diagram that the French Health Data Hub uses, an example from HDH's website below.

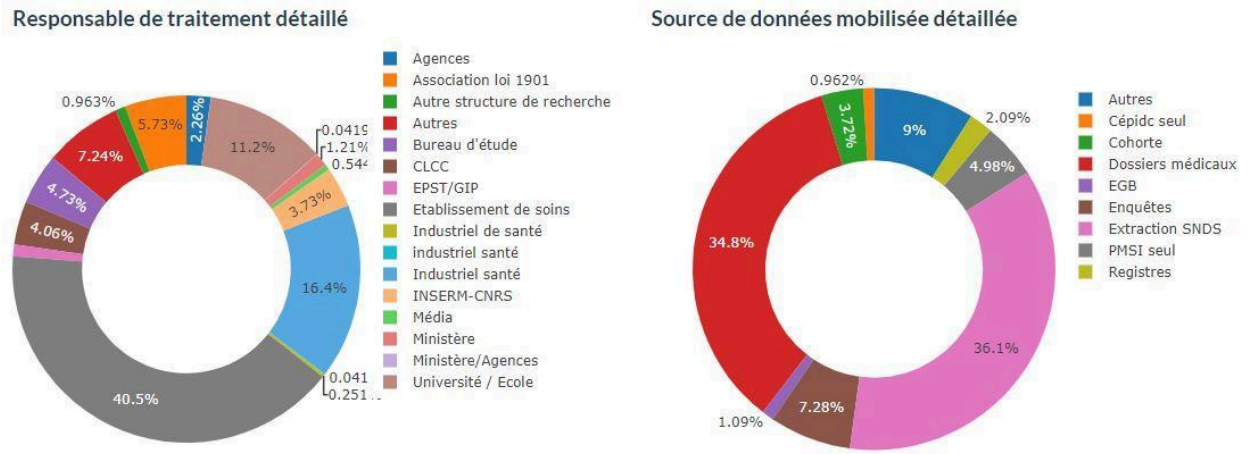

Figure 2: The circle diagrams on Health Data Hub's website illustrating the data processors and sources of data.

Finally, in terms of secondary use of electronic health data for research, it is necessary to consider that several scientific journals require the study to be reproducible for five years. It means that it should be possible for an independent researcher to end up with the same results by conducting the same research using the same data and methods. The EHDS Regulation proposal limits the maximum period of data processing to five years plus five additional years if an extension of data permit validity is granted. The reproducibility requirement may cause a problem if the data are not available anymore after publishing the results of a study.

If a data user conducts data processing during the whole five years, the user is obliged to apply for an extension permit to ensure the reproducibility. Several questions must be discussed and addressed: Is it acceptable that a user may need to apply for an extension for their data permit even though no data processing will be conducted during the validity of that extension period? What happens if, for some reason, the extension permit is not granted? Will it be possible to store the data somewhere after the period of data processing? If it will be possible, will it require the data user to have a valid data permit during that period? Should applicants factor in the possibility for their research to be published and to be subject to a reproducibility check when indicating the period for which they apply for data in their application? A regular data permit for a maximum of five years may be insufficient.

8. Conclusion

In the HealthData@EU Pilot project, the Task 7.2 succeeded in creating an EHDS and GDPR compliant common data access application form and a data request. These forms cover all the relevant pieces of information for the HDABs to assess whether to grant access to electronic health data, while not being overly burdensome for applicants or the application processors. The questions in the form were as structured as possible, finding the balance between easier processing and applicants' possibility to provide relevant and accurate information.

This Task combined information on data access application procedures from eight European countries by making use of the Landscape Analysis materials from Task 7.1. Several meetings to discuss and compile feedback on the application form, comment rounds, and workshop sessions enabled the Task leader to compile the best practices and viewpoints from several Member

States to develop a common European data access application. Some Member States, for example Finland and France, have already solid experience in developing national forms for data requests and data permits, as well as processing the applications using these forms. As a result, their data processing experts have been able to provide valuable input for this Task, stemming from practical experience and lessons learned. In addition, partners focusing on research could also provide important information regarding the usability and relevance of the form created in this pilot project. Overall, each partner brought in their own expertise, which was of great importance.

To materialise the ambitions of European wide secondary use of health data and to have a functional common metadata catalogue, each member state should work on their data registers, datasets and data descriptions and harmonise data collection practices as much as possible. Some countries are more advanced in this task than others, and establishing this catalogue will necessitate a significant effort.

Besides the above-mentioned recommendations and ideas to consider, it is important to constantly evaluate the functionality and fitness for the purpose of the application form. Data holders, health data access bodies, applicants and ethical and scientific committees all see the data access process from different angles and can provide valuable feedback for adjusting and further developing the application form as the EHDS is being implemented.

Annex 1: Common data application form

1. Introduction

1.1. Reading instructions

The form questions are **in bold**. Mandatory questions are marked with an asterisk.

The responses will be provided in a written format in an open text field if nothing else (e.g. dropdown menu) is indicated.

Regular text between questions is explanatory notes/background information for the applicant.

Notes on the right side starting with an "(info)" text are info buttons that would pop up when the applicant hovers over. They include clarifications to the questions or further guide the applicant when filling in the form.

Notes on the right side **without** "(info)" text at the beginning are descriptions of the functionalities of the form based on the applicant's answers or clarifications for technical development of the form.

Underlined text means a hyperlink/a button, such as for attaching files.

Grey text describes functionalities of the form (e.g. if the applicant selects "yes" or "no", the grey text indicates which fields this selection activates in the form) and contents of dropdown menus.

Red text is used to mark unknown information that needs to be completed once an agreement of the EHDS Regulation is achieved.

Radio button = A graphical element that allows the applicant to choose only one option. Illustrated with round bullet points. Additionally, simple Yes/No questions on the form can be implemented with radio buttons.

Checkboxes = Graphical elements that allow the applicant to choose multiple answer options. Illustrated with square bullet points or grey texts saying: "(checkbox)".

1.2. Glossary

- Applicant = The person applying for data, the data user (if access is granted).
- Controller [1]= The natural or legal person, public authority, agency or other body which, alone or jointly with others ('joint controllership'), determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law.
- Data access application = An application seeking to access personal level electronic health data for secondary use in an anonymised or a pseudonymised format.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679

- Data extraction description = A document outlining which data are applied for specifying the geographical location(s), register(s), dataset(s) and variable(s). An attachment that must be filled in and attached to the data access application form.
- Data holder = A person, an entity or a body registering and storing health data. The data holder makes electronic health data available as per the EHDS Regulation. It also communicates to the health data access body a general description of the dataset it holds.
- Data registry = A collection of data. Data registry is managed by an authority or an organisation.
- Data request = An application for accessing electronic health data for secondary use in an anonymised statistical format.
- Data user = A natural or a legal person who has lawful access to personal or non-personal electronic health data for secondary use.
- Extraction method = A way of retrieving data. For example, retrieving a random sample of a defined group of data subjects, retrieving all the data subjects fulfilling a defined set of criteria, or another method.
- General Data Protection Regulation = It sets out detailed requirements for companies and organisations on collecting, storing and managing personal data. It applies both to European organisations that process personal data of individuals in the EU, and to organisations outside the EU that target people living in the EU. Acronym: GDPR.
- Health data access body = Bodies that are responsible for processing the health data applications and granting access to electronic health data for secondary use if the application is accepted. Acronym: HDAB.
- Regulation on the European Health Data Space (EHDS) = A legal document establishing the framework and rules regarding the creation and functioning of a common space where natural persons can easily control their electronic health data. It will also enable researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy.
- Study cohort = The group of people whose data are studied. Also known as 'study population' or 'group of data subjects'.

1.3. General information about data access

Data access can only be authorised if the data are to be used for one or more of the following purposes:

a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices

b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates

c) to produce national, multi-national and Union level official statistics related to health or care sectors

d) education or teaching activities in health or care sectors

e) scientific research related to health or care sectors

f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

Data access cannot be granted for prohibited purposes. Prohibited uses of data are:

a) taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons

b) taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums

c) advertising or marketing activities towards health professionals, organisations in health or natural persons

d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit

e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.

1.4. Type of data access

Access is granted primarily to electronic health data in an aggregated anonymous format (via a data request form). Access to personal level electronic health data in pseudonymised format can be given (via a data permit application form) in cases where the purpose of data processing cannot be achieved with anonymised data.

1.5. Availability of data in different EU countries

The availability of data in different EU countries vary in terms of amount, scope and organisation of data. You can browse the available data in the EHDS metadata catalogue.

1.6. Penalties for misuse of electronic health data

Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in the European Health Data Space Regulation. Health data access bodies have the power to revoke the data permit issued and stop the affected electronic health data processing operation carried out by the data user. You can find more information on the correct use and penalties for misuse of electronic health data here.

1.7. Attachments

You are required to attach some documents to your application, such as the extraction description form. The number of necessary attachments may vary depending on the country and data holder from which you are requesting data. For example, some countries require applicants to acquire an ethical approval by an ethics committee before granting data. Once you indicate the purpose of data use, the country/countries and the data holders from which you seek data, the application form will show you which documents you need to attach to your application.

1.8. Fees

The health data access bodies and single data holder(s) may charge fees for making electronic health data available for secondary use. Any fees shall include and be derived from the costs related to conducting the procedure for requests, including for assessing a data application or a data request, granting, refusing or amending a data permit or providing an answer to a data request. A processing fee will be charged for processing the application. It will also apply in case of a cancelled request or a negative decision. (This part will be updated once there is more concrete information on the fees.)

1.9. Data privacy statement

By filling in the application form, you accept that your personal data will be collected and used for processing the application and delivering you the requested data, if granted. The use of your personal data will be limited strictly to the amount necessary.

1.10. Data access application and data request

What kind of data do you need? Choose the corresponding application form.

- I need data in an anonymised statistical format. I understand that I will have no access to the electronic health data used to provide the requested data.
- I need personal level data in an anonymised or a pseudonymised format. I am aware that processing this kind of data is possible only in an audited secure processing environment.

2. Data access application form

2.1. Selecting the health data access body

Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice.

To which health data access body/bodies do you want to submit the application? (dropdown menu[2])

2.2. Public information on the project

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.

- **Project name***
- **Project leader name[3]*** (organisation, institution, private sector entity, or a natural person)
- **Country of the project leader*** (dropdown menu)
- **Purpose for which the data will be used*** (dropdown menu[4])
- **The research focuses on the following objectives** (dropdown menu[5])
- **Area of research** (dropdown menu[6])

[2] A list of health data access body options in a drop-down menu. E.g. If an applicant seeks data from Finland, Spain and Belgium, the applicant can choose a health data access body among the bodies in those countries.
[3] Person responsible for data use.
[4] purposes from the EHDS Regulation
[5] The research focuses on the following objective(s) (an example of what options the dropdown menu could list - to be checked before implementing the EHDS): Diagnostics; Epidemiology; Patient management; Patient safety; Prevention and treatment; Public health policy; Organisation of healthcare establishments; Understanding diseases, Other, which?
[6] The research concerns the following medical or other field(s) (an example of what options the dropdown menu could list - to be checked before implementing the EHDS): Allergology; Anatomy and cytology; Anaesthesiology and intensive care; Biology; Cardiology; Deficiencies and handicaps; Dermatology and venereology; Ear, nose and throat; Economics; Emergency medicine; Endocrinology and metabolism; Gastroenterology and hepatology; General medicine; Geriatrics; Gynaecology and obstetrics Haematology; Immunology; Infectious diseases; Internal medicine; Neurology; Nuclear medicine; Occupational medicine; Odontology; Oncology; Ophthalmology; Paediatrics; Physical and rehabilitation medicine; Pneumology; Psychology and psychiatry; Radiology and medical imaging; Rare diseases;

- **Description of the data you will use.*** Describe it on the level suitable to be published on the health data access body's website. If, for some reason, the nature of your project does not let you provide a description, explain here the reason(s). This explanation of the reason(s) will not be published.
- **Summary of the project[7].*** (max. 500 characters) If, for some reason, the nature of your project does not let you provide a summary, explain here the reason(s). This explanation of the reason(s) will not be published.

2.3. Applicant and contact person information

- **Are you applying for data on behalf of a public sector body or a European Union institution, body, office or agency?*** Yes/No
    - If yes: Are you applying for data for carrying out tasks enshrined in the mandate [8]of your organisation/institution?* Yes/No
- **Applicant information*** [9] (radio buttons for 'legal person' and 'natural person')
    - **Legal person**:
        - **Full name***
        - **Postal address*** (street name and number, zip code, city/town, country)
        - **Business ID or similar***
        - **Contact person information** (Contact person refers to the person who responds to enquiries concerning the application. The contact person's details can be forwarded to the controller during the processing of an application if additional information is required for defining the data extraction).
            - **Full name***
            - **Job title** (if related to the project and data processing)
            - **E-mail address***
            - **Phone number*** (including the country code)
            - **What is the relationship between the contact person and the applicant?*** E.g. an employee applying for data on behalf of their organisation.
    - **Natural person**[10]:
        - **Full name***
        - **Postal address*** (street name and number, zip code, city/town, country)
        - **Phone number*** (including the country code)

Rheumatology; Sociology; Traumatology; Urology, andrology and nephrology; Other, which?

[7] If, for some reason, the nature of your project does not let you provide a summary, explain here the reason(s). This explanation of the reason(s) will not be published.

[8] Tasks in your organisation's/institution's mandate mean tasks based on national or European Union law.

[9] - Natural person = a physical person, an individual human being
- Legal person = A company, organisation or an association

[10] If you choose this option, you confirm that you apply for data as a private person without any affiliation.

2.4. Payment details

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:

- **Payer's full name***
- **Payer's postal address*** (street name and number, zip code, city/town, country)
- **Payer's e-mail address***
- **Payer's phone number*** (including the country code)
- **Invoice type*** (radio buttons)
    - paper
    - electronic
- **Invoice reference number***
- If electronic invoice: **E-invoice address (EDI or IBAN)***
- If legal person: **Operator ID***
    - **Name of the organisation***
    - **Business ID of the organisation***
    - **VAT number***
    - **Peppol code** (if applicable)

2.5. Purpose of data use

Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with the following purposes (as per Article 34(1)) listed below).

- **Select the option corresponding to your purpose of data use:*** (checkbox)
    - a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices
    - b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates
    - c) to produce national, multi-national and Union level official statistics related to health or care sectors
    - d) education or teaching activities in health or care sectors
    - e) scientific research related to health or care sectors[11]
    - f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

[11] If "research" is selected as use purpose, the research related questions (below) appear. If another use purpose is selected, the "if not research" questions appear.

- g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices
- h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

- **Why[12] are the data you are applying for needed for the indicated purpose of use?*** (Max. 1000 characters)
- **What is the aim and topic of your project?*** (Max. 1000 characters)
- If a public sector/EU body:[13] **Specify the legal basis, for example the relevant legislation, which defines the tasks falling within your mandate and confirm that your planned use of the data is to facilitate such tasks***
- If a public sector/EU body: **Provide a link to the supporting documentation as evidence of the legal basis***
- If not research:
  - **Provide a summary of your plan for using the data.*** The summary must be a maximum of two pages long and written in one of the official EU languages. Attach a file.
  - Person responsible for data use:
    - **Full name***
    - **Job title***
    - **Affiliation***
- If research (option (e) is chosen):
  - **Provide a summary of your research plan.*** The summary must be a maximum of two pages long and written in one of the official EU languages[14]. Attach a file
  - Person responsible for the research:
    - **Full name***
    - **Job title***
    - **Affiliation***
- **Select the format of the electronic health data to be made available*** (dropdown menu) anonymised/pseudonymised
  - If pseudonymised: I am aware that in order to apply for pseudonymised data, I must

[12] Explain here why the amount and type of data that you apply for are necessary for your data use purpose.
[13] No data utilisation plan is needed from these applicants.
[14] The official EU languages are: Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish.

- a) explain how I will comply with Article 6(1) of the General Data Protection Regulation (or Article 5(1) of the EU Data Protection Regulation if an EU institution, body, office or agency is applying for data)
- b) assess ethical aspects of processing the data, where applicable and in line with national law or applicable laws.

- If pseudonymised: **Why do you need pseudonymised data for your project?***

2.6. Description of the dataset needed

In this section, you need to provide a description of the requested dataset, clearly indicating which datasets 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 Regulation (Article 5(1c)). The health data access body evaluates carefully if your requirements are in line with the GDPR data minimisation principle.

- **If you have been in contact with someone from the health data access body regarding the data you seek, list here the names and the e-mail addresses of these persons**
- **How will the data from different sources be linked?*** E.g. based on personal identification code. If some kind of other linkage method is used, describe that here.

2.6.1. Defining the extraction criteria for the study cohort

- **How is the study cohort formed?*[15]** (four radio buttons numbered for clarity in this document)

  (1) The study cohort will be formed based on the criteria given below

  (2) The study cohort has already been formed[16]

  If the applicant selects the 2nd option:

  - **Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed***
  - **If you wish to use a study cohort based on your own previous survey study, has the study cohort been formed based on informed consents of study participants?*[17]**Yes/No
  - If yes: **Does the informed consent cover the requested registry extractions?*** Yes/No

[15] Applicants can choose one of the options below.
If they tick the box "The study cohort has already been formed", the question indicating the basis on which the study cohort was done will appear a few questions below.
[16] E.g. the study cohort is formed based on a survey study already conducted or based on register data from a data holder not included in the EHDS.
[17] E.g. cohort formed based on a survey study or a clinical study, to which register-based data will be linked under the EHDS Regulation.

- If yes: **Attach the consent and information letter that you have sent to the study subjects.*** Do not attach forms that are filled in because they include personal data. Attach a file
- If yes: **I confirm that the data permit has been granted for this research project*** (checkbox)
- If yes: **Issuer, date, validity period and the code/other identifying information of the permit decision for the study cohort***[18]
- If yes: **Attach a permit decision covering the extraction of the study cohort data in this section*** Attach a file
- If not: **Describe how the study cohort was obtained and the reasons for the lack of data permit/consent***
- **Have you provided information of the data use to the corresponding subjects?***[19] E.g. shared information of the data use on a project website. Yes/No
- If yes: **How?***
- If not: **Why not?***

(3) The study cohort will consist of these two: a new cohort formed based on the criteria given below and an already formed cohort

If the applicant selects the 2nd or the 3rd option, the questions below will appear:

- **Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed***
- **Who will deliver the information on the study cohort to the health data access body?*** This can be the applicant or someone else. **Full name, e-mail, phone number*** (including the country code) This person will receive instructions on how to deliver the data through the common EHDS portal – to be edited once information is available.

(4) The study cohort will be the whole population of a country/countries indicated at the beginning of this form

If the applicant selects the 4th option:

- **Provide arguments why you need data of a whole population/whole populations***

Make sure to define the formation of the study cohort clearly enough and delimit the cohort size according to the intended use. Pay special attention to which registers the study cohort is extracted from, and the inclusion and exclusion criteria for the study cohort. For example, a geographic definition may mean the place of residence, the place of birth, the place of work, or the place where services are used.

- **Size of the study cohort*** (text field)

(radio buttons)

[18] E.g. a research permit granted by another authority, covering the formation of the cohort and possible gathering of non-EHDS data regarding the study subjects.

[19] For further information, see the General Data Protection Regulation articles 13 and 14: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679

  - This is an estimation of the size of the study cohort.
  - This is the exact size of the study cohort.
- **Why do you need a study cohort of this size for your project?***
- **From which country/countries do you seek data?*** (dropdown menu) Countries[20]
- **If you do not seek data from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data**

  The requirements related to the ethical review to be shown here, based on the country (and region) selection
- **From which data holder(s) will the data be extracted?*** (dropdown menu) Dataholders[21]

  The required attachments to be listed here, based on the country (and region) selection and/or the data holder(s)
- **From which database(s) or registry/registries will the data be extracted?*** (dropdown menu) Databases/registries[22]
- **From which dataset(s)/register(s) will the data be extracted?*** (dropdown menu) Datasets/registers[23]
- **If the information is available, list the variables to be used in the data extraction.** Use the exact terms provided by the respective data holder(s) in the metadata catalogue.
- **For which time period(s) will the datasets be extracted?***
- **Extraction method* (dropdown menu)** random sample / all the people fulfilling the criteria / other sample
- If 'other sample': **Describe the sampling method***
- If 'random sample' or 'other sample': **Sample size***[24]
- **Describe the inclusion criteria for study cohort extraction***[25]
- **Describe the potential exclusion criteria for study cohort extraction**

Data extraction times and order for the study cohort

- **How often does the data need to be extracted? *** (dropdown menu) once / multiple times
- If multiple times: **The data needs to be extracted every ***[26] (dropdown menu) year / half a year / quarter / other, specify

[20] Possible to choose one or more.
[21] Possible to choose one or more.
[22] Possible to choose one or more.
[23] Possible to choose one or more.
[24] Open text field. Answers can be for example: 100 000 persons or 50% of the people fulfilling the criteria.
[25] Remember to clarify here any inclusion criteria that may be ambiguous. For example, if you want to include data subjects of certain age, clarify based on which variable the age should be calculated and at which time point.
[26] Note that the maximum frequency of data extraction is every quarter.

If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data gathering method may change during the review period in some cases.

- **Provide more information on the study cohort extracting periods/times***
- **If it affects the results of the data extraction, in which order will the study cohort data be extracted?**[27]

2.6.2. Defining the extraction criteria for controls

- **Will controls be extracted for the study cohort defined above?*** Yes/No

  If not, no further questions regarding controls
- **Will the same data as for the study cohort be extracted for controls?*** Yes/No
- If not:
  - **From which country will the data for controls be extracted?*** (dropdown menu) Countries
  - **If you do not seek data for controls from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data**
  - **From which data holder(s) will the data for controls be extracted?*** (dropdown menu) Data holders
  - **From which database(s)/registry/registries will the data for controls be extracted?*** (dropdown menu) Databases/Registries
  - **From which dataset(s)/register(s) will the data for controls be extracted?*** (dropdown menu) Datasets/Registers
  - **If the information is available, list the variables to be used in the data extraction.** Use the exact terms provided by the respective data holder(s) in the metadata catalogue.
  - **For which time period(s) will the datasets be extracted?***
  - **Specify the extraction criteria for controls, e.g. matching criteria***
- **Size of the control group*** (text field)

  (radio buttons)
  - This is an estimation of the size of the control group.
  - This is the exact size of the control group.
- **How many controls are extracted per person belonging to the study cohort?***
- **Describe the inclusion criteria for controls' extraction***
- **Describe the potential exclusion criteria for controls' extraction**
- **If the group of controls has been formed based on a previously issued permit, list here the issuer of the permit decision, date, validity period and permit number**

Data extraction times and order for controls

[27] Provide a numbered list of extraction phases. For example: 1. Data holder A; 2. Data holder B; 3. Data holder C

- **Will the data for controls be extracted at the same time and in the same order as the data for the study cohort?*** Yes/No

  If yes, no further questions in this 'times and order section'

- If not:
  - **How often does the data need to be extracted? *[28]** (radio buttons) once / multiple times
  - If multiple times: **The data needs to be extracted every *[29]** (dropdown menu) year / half a year / quarter / other, specify

    If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.
  - **Provide more information on the extracting periods/times***
  - **If it affects the results of the data extraction, in which order will the controls' data be extracted?[30]**

2.6.3. Defining the extraction criteria for relatives

- **Will relatives be extracted for the study cohort?*** Yes/No

  If not, no further questions regarding relatives.

- **Will the same data as for the study cohort be extracted for relatives?*** Yes/No

  If not:
  - **From which data holder(s) will the data for relatives be extracted?*** (dropdown menu) Data holders
  - **From which database(s)/registry/registries will the data for relatives be extracted?*** (dropdown menu) Databases/Registries
  - **From which dataset(s)/register(s) will the data for relatives be extracted?*** (dropdown menu) Datasets/Registers
  - **If the information is available, list the variables to be used in the data extraction.** Use the exact terms provided by the respective data holder(s) in the metadata catalogue.
  - **For which time period(s) will the datasets be extracted?***
  - **Define the relationship of the relatives to the person belonging to the study cohort*** (e.g. grandparents, biological parents, mother)

- **If the group of relatives have been formed on the basis of a previously issued permit(s), list here the issuer of the permit decision, date, validity period and any identifying information**
- **Size of the group of relatives*** (text field)

  (radio buttons)

[28] In case of recurrent extraction, provide information on each data extraction process separately in the order instructions.
[29] Note that the maximum frequency of data extraction is every quarter.
[30] Provide a numbered list of extraction phases. For example: 1. Data holder A; 2. Data holder B; 3. Data holder C

- This is an estimation of the size of the group of relatives.
- This is the exact size of the group of relatives.

Data extraction times and order for relatives

- **Will the data for relatives be extracted at the same time and in the same order as the data for the study cohort?*** Yes/No

  If yes, no further questions in this 'times and order section'
- If not: **How often does the data need to be extracted?***[31] (radio buttons) once / multiple times
- If multiple times: **The data needs to be extracted every *** [32](radio buttons) year / half a year / quarter / other, specify

  If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.
- **Provide more information on the extracting periods/times***
- **If it affects the results of the data extraction, in which order will the relatives' data be extracted?**[33]

2.7. Other data to be combined

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.

- **Will the data you are applying for be combined with data you have already obtained or data from other sources?*** Yes/No
- If yes: List the other data to be combined and the sources of this data
  - **Country/Countries***
  - **Data holder(s)***
  - **Database(s)/Registry/Registries***
  - **Dataset(s)/Register(s)***
  - **Provide information on data to be combined and the planned combination method***[34]

[31] In case of recurrent extraction, provide information on each data extraction process separately in the order instructions.
[32] Note that the maximum frequency of data extraction is every quarter.
[33] Provide a numbered list of extraction phases. For example: 1. Data holder A; 2. Data holder B; 3. Data holder C
[34] Provide information on the following, to the extent applicable: data set, number of the files, format of the files, size of the files, special notes (are there direct/indirect identifiers, data should be

- **List here any other data permits issued for the same project**. The permits must be valid at the time data are processed.
- **Other permits: issuer, date of issue, expiry date, identification information**
- **If the datasets involve permits issued by other parties or they have been collected with consent, attach the permit documents here** Attach a file
- **Do you have other pending permit applications? *[35]** Yes/No
- If yes: **Date of submitting the application, issuer, identification code***

2.8. Data processing, data protection and safeguards to prevent unauthorised use of data

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.

- **List here all the technical requirements you have for the secure processing environment***
- **If you already know which processing environment you want to use, what is its name and where is it located[36]?**

The health data access body will deliver the data once your application is processed if you are granted a data permit. The health data access body will retain the pseudonymisation key and the extraction terms and documentation used to generate the data.

The data permit will be granted only for the duration necessary to fulfil the requested purposes. The permit can be granted for a maximum period of 5 years. This duration may be extended once, at the request of the data user, based on arguments and documents justifying the extension (EHDS Regulation proposal, Article 46(9)). Where needed, the period of use may be extended by applying for an amendment of the data permit.

- **When do you need the data? [37]*** (Radio buttons)
  - As soon as possible after this application has been processed
  - Later, when? (text field)
- If 'later, when': **date***
- If a public sector or EU body applicant: **Provide information on the period for which the data can be accessed***
- If a public sector or EU body applicant: **What is the frequency of that access or the frequency of the data updates?***
- Any other applicant except public sector or EU bodies: **What are the estimated start and end dates of the period during which the electronic health data is needed for processing?*[38]** date–date

pseudonymised, etc.)

[35] Provide information on the following, to the extent applicable: data set, number of the files, format of the files, size of the files, special notes (are there direct/indirect identifiers, data should be pseudonymised, etc.)

[36] Provide here the name and the website address of the secure processing environment.

[37] In general, the health data access body will conduct the data extraction as soon as your application has been processed. If you wish to receive the data later, indicate it here.

[38] This period can be five years. With additional permit, the original permit can be extended for another

- **If you need to store the data after processing, indicate here the period of inactive data storage**[39] date–date
- **Will the data be transferred** [40]**outside the EU or the EEA?*** Yes/No
- If yes:
    - **In which country/countries outside the EU/EEA will the data be processed?*** (dropdown menu) Countries
    - **Why will the data be transferred outside the EU or the EEA?***
    - **What is the legal basis**[41] **for transferring the data outside the EU or EEA?*** (radio button)
        - The country/territory/international organisation of transfer ensures an adequate level of protection as per a decision by the European Commission (GDPR Article 35)
        - The data controller or processor has provided appropriate safeguards, and enforceable data subject rights and effective legal remedies for data subjects are available (GDPR Article 46). **These safeguards are provided by*** (dropdown menu)
            - a legally binding and enforceable instrument between public authorities or bodies
            - binding corporate rules in accordance with Article 47
            - standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93(2)
            - standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93(2)
            - an approved code of conduct pursuant to Article 40 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights
            - an approved certification mechanism pursuant to Article 42 together with binding and enforceable commitments of the

five years.

[39] Please note that storing the data may have a cost.

[40] The European Data Protection Board (EDPB) has identified three cumulative criteria to qualify a processing operation as a transfer:
1) A controller or a processor ("exporter") is subject to the GDPR for the given processing.
2) The exporter discloses by transmission or otherwise makes personal data, subject to this processing, available to another controller, joint controller or processor ("importer").
3) The importer is in a third country, irrespective of whether or not this importer is subject to the GDPR for the given processing in accordance with Article 3, or is an international organisation.
More information: https://edpb.europa.eu/system/files/2023-02/edpb_guidelines_05-2021_interplay_between_the_application_of_art3-chapter_v_of_the_gdpr_v2_en_0.pdf

[41] More information in the General Data Protection Regulation Chapter 5: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#d1e4227-1-1

controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights

- Other exceptional legal basis (in the absence of appropriate safeguards pursuant to article 46) (dropdown menu)
  - the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards
  - the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request
  - the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person
  - the transfer is necessary for important reasons of public interest
  - the transfer is necessary for the establishment, exercise or defence of legal claims
  - the transfer is necessary in order to protect the vital interests of the data subject or of other persons, where the data subject is physically or legally incapable of giving consent
  - the transfer is made from a register which according to Union or Member State law is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down by Union or Member State law for consultation are fulfilled in the particular case

- **Which organisation(s) or individual will be the controller [42]of the data to be formed based on this application?***
  - If any other applicants than EU bodies: **How do you comply with the principle of data minimisation (EU General Data Protection Regulation) [43]when processing the data?***
  - If an EU body applicant: **How do you comply with the principle of data minimisation (EU Data Protection Regulation)[44] when processing the data?***
  - **To proceed with this application, you need to confirm the following statements*** (checkboxes)

[42] A data controller determines the purposes and means of processing personal data. In other words, the data controller decides the how and why of a data processing operation. A data controller can be a legal person, for example a business, an SME, a public authority, an agency or other body.
More information: https://edpb.europa.eu/sme-data-protection-guide/data-controller-data-processor_en
[43] GDPR Article 5(1)c: "Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')"
[44] EU DPR Article 4(1c) "Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')"

- I confirm that if the health data access body grants me the data I am applying for, I will use it only for the purpose(s) stated in this application form.
- I understand that copying the data from the secure processing environment is prohibited.
- I understand that taking any screenshots or photos of the device screen, once in the secure processing environment, is prohibited.
- I have sufficient safety measures (such as a firewall) in place to protect the different networks to which the devices containing data are connected.
- I understand that re-identification attempts are prohibited, and that the health data access body can impose penalties according to Article 43 of the European Health Data Regulation.

Only the people mentioned in the data permit will be granted access to process the data in the secure processing environment.

- **List the full names, affiliations and e-mail addresses of all the people who will be processing the data***

Lawfulness of processing

If a natural person or a public sector authority is applying for data in pseudonymised format:

- Processing of the personal data that you are applying for with this application form shall be lawful only if and to the extent that at least one of the following applies (in accordance with Article 6(1) of the EU's General Data Protection Regulation, Regulation (EU) 2016/679):
  - (a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
  - (b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
  - (c) processing is necessary for compliance with a legal obligation to which the controller is subject;
  - (d) processing is necessary in order to protect the vital interests of the data subject or of another natural person;
  - (e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
  - (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
    - Point (f) shall not apply to processing carried out by public authorities in the performance of their tasks.
- **What is the legal basis for processing the personal data that you are applying for with this application form?*** (dropdown menu)

- (e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- (f) Processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
- Other, which? (free text field)

- If the applicant has filled in section 7: What is the legal basis for processing the other data that you will combine with data applied for in this application (section 7)?* (dropdown menu)
  - (e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
  - (f) Processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
  - Other, which? (free text field)
- If a European Union institution, body, office or agency is applying for data in pseudonymised format: Processing of the personal data that you are applying for with this application form shall be lawful only if and to the extent that at least one of the following applies (in accordance with Article 5(1) of the EU's Data Protection Regulation, Regulation (EU) 2018/1725):
  - (a) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body;
  - (b) processing is necessary for compliance with a legal obligation to which the controller is subject;
  - (c) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
  - (d) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
  - (e) processing is necessary in order to protect the vital interests of the data subject or of another natural person.
- **What is the legal basis for processing the personal data that you are applying for with this application form?*** (dropdown menu)
  - (a) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body
  - Other, which? (free text field)
- If the applicant has filled in section 7: **What is the legal basis for processing the**

other data[45] that you will combine with data applied for in this application (section 7)?* (dropdown menu)

- (a) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body
- Other, which? (free text field)

- If research: **If your research requires a research permit from your affiliation organisation, attach the research permit** Attach a file

2.9. Additional information

- **Further information[46] or any additional notes**
- **An additional attachment[47]** Do not attach health or personal data to this application.

2.10. Confirmation of information

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.

To submit your application, you need to confirm the following:*

- I am aware that a processing fee will be charged for processing my application. It will also apply in case of a cancelled request or negative decision.
- I am aware that data holder(s) may charge a fee for providing the data.
- I confirm that the information I have provided is correct.

[45] This question will only appear if applicants indicate that they will combine the applied EHDS data with other data (outside the EHDS).
[46] Here you can provide further information on any of the sections in your application. Indicate the number of section and the question to which your comment refers.
Suggestion for the technical implementation: Alternatively, there could be a way to allow the applicant to link information to specific parts of the form to facilitate HDABs job.
[47] If you have any other attachment that you deem relevant regarding the processing of your application and necessary for the Health Data Access Body to see, attach it here. Describe its relevance in the text field above.

3. Data request form

3.1. Selecting the health data access body

Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice.

To which health data access body/bodies do you want to submit the application?[48] (dropdown menu)

3.2. Public information on the project

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 a 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 data 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.

- **Project name***
- **Project leader name***[49] (organisation, institution, private sector entity, or a natural person)
- **Country of the project leader*** (dropdown menu)
- **Purpose for which the data will be used*** (dropdown menu)[50]
- **The research focuses on the following objectives** (dropdown menu)[51]
- **Area of research** (dropdown menu)[52]

[48] A list of health data access body options in a drop-down menu. E.g. if the applicant seeks data from Finland, Spain and Belgium, the applicant can choose a health data access body among the bodies in those countries.
[49] Person responsible for data use.
[50] Use purposes from the EHDS Regulation
[51] The research focuses on the following objective(s) (an example of what options the dropdown menu could list - to be checked before implementing the EHDS): Diagnostics; Epidemiology; Patient management; Patient safety; Prevention and treatment; Public health policy; Organisation of healthcare establishments; Understanding diseases; Other, which?
[52] The research concerns the following medical or other field(s) (an example of what options the dropdown menu could list - to be checked before implementing the EHDS): Allergology; Anatomy and cytology; Anaesthesiology and intensive care; Biology; Cardiology; Deficiencies and handicaps; Dermatology and venereology; Ear, nose and throat; Economics; Emergency medicine; Endocrinology and metabolism; Gastroenterology and hepatology; General medicine; Geriatrics; Gynaecology and obstetrics; Haematology; Immunology; Infectious diseases; Internal medicine; Neurology; Nuclear medicine; Occupational medicine; Odontology; Oncology; Ophthalmology; Paediatrics; Physical and rehabilitation medicine; Pneumology; Psychology and psychiatry; Radiology and medical imaging; Rare diseases;

- **Description of the data you will use*** Describe it on the level suitable to be published on the health data access body's website. If, for some reason, the nature of your project does not let you provide a description, explain here the reason(s). This explanation of the reason(s) will not be published.
- **Summary of the project*[53]** (max. 500 characters) If, for some reason, the nature of your project does not let you provide a summary, explain here the reason(s). This explanation of the reason(s) will not be published.

3.3. Applicant and contact person information

- **Are you applying for data on behalf of a public sector body or a European Union institution, body, office or agency?*** Yes/No
- If yes: **Are you applying for data for carrying out tasks enshrined in the mandate [54]of your organisation/institution?*** Yes/No

Applicant information* (radio buttons for 'legal person' and 'natural person')

- Legal person:
  - **Full name***
  - **Postal address*** (street name and number, zip code, city/town, country)
  - **Business ID or similar***

Contact person information

Contact person refers to the person who responds to enquiries concerning the application. The contact person's details can be forwarded to the controller during the processing of an application if additional information is required for defining the data extraction.

- **Full name***
- **Job title** (if related to the project and data processing)
- **E-mail address***
- **Phone number*** (including the country code)
- **What is the relationship between the contact person and the applicant?*** E.g. an employee applying for data on behalf of their organisation.
  - Natural person:[55]
    - **Full name***
    - **Postal address*** (street name and number, zip code, city/town, country)
    - **Phone number*** (including the country code)

Rheumatology; Sociology; Traumatology; Urology, andrology and nephrology; Other, which?

[53] If, for some reason, the nature of your project does not let you provide a summary, explain here the reason(s). This explanation of the reason(s) will not be published.

[54] Tasks in your organisation's/institution's mandate mean tasks based on national or European Union law.

[55] If you choose this option, you confirm that you apply for data as a private person without any affiliation.

3.4. Payment details

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

- **Payer's full name***
- **Payer's postal address*** (street name and number, zip code, city/town, country)
- **Payer's e-mail address***
- **Payer's phone number*** (including the country code)
- **Invoice type*** (radio buttons)
    - paper
    - electronic
- **Invoice reference***
- If electronic invoice: E-invoice address (EDI or IBAN)*
- If legal person:
    - **Operator ID***
    - **Name of the organisation***
    - **Business ID of the organisation***
    - **VAT number***
    - **Peppol code** (if applicable)

3.5. Purpose of data use

Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with the following purposes (as per Article 34(1)) listed below.

- **Select the option corresponding to your purpose of data use:**
    - a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices
    - b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates
    - c) to produce national, multi-national and Union level official statistics related to health or care sectors
    - d) education or teaching activities in health or care sectors
    - e) scientific research related to health or care sectors[56]

[56] If "research" is selected, the research related questions (below) appear. If not, the 'if not research' questions appear.

- f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices
- g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices
- h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

- **Why are the data requested with this application needed for the indicated purpose of use?*** (Max. 1000 characters)
- **What is the aim and topic of your project?* (**Max. 1000 characters)
- If a public sector/EU body[57]: **Specify the legal basis, for example the relevant legislation, which defines the tasks falling within your mandate and confirm that your planned use of the data is to facilitate such tasks***
- If a public sector/EU body: **Provide a link to the supporting documentation as evidence of the legal basis***
- If not research:
  - **Provide a summary of your plan for using the data*** The summary must be a maximum of two pages long and written in one of the official EU languages. Attach a file.
  - Person responsible for data use:
    - **Full name***
    - **Job title***
    - **Affiliation***
- If research (option (e) is chosen):
  - **Provide a summary of your research plan*** The summary must be a maximum of two pages long and written in one of the official EU languages. Attach a file
  - Person responsible for the research:
    - **Full name***
    - **Job title***
    - **Affiliation***

3.6. Description of the dataset needed

In this section, you need to provide a description of the requested dataset, clearly indicating which datasets the application concerns.

[57] Explain here why the amount of data that you apply for is necessary for your data use purpose. Justify and describe how the contents of the requested statistics correspond to the purpose of use stated in the application and meet your data requirements.

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 Regulation[58] (Article 5(1c)). The health data access body evaluates carefully if your requirements are in line with the GDPR data minimisation principle.

- **If you have been in contact with someone from the health data access body regarding the data you seek, list here the names and the e-mail addresses of these persons**

3.6.1 Defining the extraction criteria for the study cohort

- **Size of the study cohort*** (text field)
  (radio buttons)
  - This is an estimation of the size of the study cohort.
  - This is the exact size of the study cohort.
- **Why do you need a study cohort of this size for your project?***
- **From which country/countries do you seek data?*** (dropdown menu) countries[59]
- **If you do not seek data from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data**
  The requirements related to the ethical review to be shown here, based on the country (and region) selection
- **From which data holder(s) will the data be extracted?*** (dropdown menu) Dataholders[60]
  The required attachments to be listed here, based on the country (and region) selection and/or data holder(s)
- **From which database(s) or registry/registries will the data be extracted?*** (dropdown menu) Databases/registries[61]
- **From which dataset(s)/register(s) will the data be extracted?*** (dropdown menu) Datasets/registers[62]
- **If the information is available, list the variables to be used in the data extraction.** Use the exact terms provided by the respective data holder(s) in the metadata catalogue.
- **For which time period(s) will the datasets be extracted?***
- **Extraction method*** (dropdown menu) random sample / all the people fulfilling the criteria / other sample
  - If 'other sample': **Describe the sampling method***
  - If 'other sample' or 'random sample': **Sample size***[63]

[58] If an EU body applicant: Refer here to EU DPR Art. 4(1c).
[59] Possible to choose one or more
[60] Possible to choose one or more
[61] Possible to choose one or more
[62] Possible to choose one or more
[63] Open text field. Answers can be for example: 100 000 persons or 50% of the people fulfilling the criteria.

- **Describe the inclusion criteria for study cohort extraction*[64]**
- **Describe the potential exclusion criteria for study cohort group extraction**

Tabulation plan

For each statistic you request, attach an example Excel (or equivalent) table. If you know the variables to be used, define them in the respective rows and columns. In addition, write down the following information for each table:

- register to be used
- possible study cohort
- information on the required variables (if available)
- formation of variables where they cannot be directly accessed from the database
- desired direction of aggregation of percentages
- order in which tables are generated when previously generated tables are used to create other tables
- any other relevant factor related to generating the required table(s)

Attach a tabulation plan here*

3.7. Extraction description and compilation of statistics

A health data access body shall only provide the data you request only in an anonymised statistical format, if your data request is accepted. Due to anonymity, the data user shall have no access to the electronic health data used to provide this answer.

All the information you request must be rendered down to a general level in order to avoid small cell counts with high re-identification potential.

- **How often does the data need to be extracted?*** (dropdown menu) once, multiple times[65]
    - If 'multiple times': **The data needs to be extracted every*** (radio buttons) year/quarter
- **Provide more information on the extracting periods/times**

  If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data gathering method may change during the review period in some cases.
- If a public sector body/EU body applicant: **What is the frequency of any updates to the data which are required?***

[64] Remember to clarify here any inclusion criteria that may be ambiguous. For example, if you want to include data subjects of certain age, clarify based on which variable the age should be calculated and at which time point

[65] If the applicant selects multiple times, the question below appears.

3.8. Additional information and attachments

- **Further information[66] or any additional notes**
- **An additional attachment.[67] Do not attach health or personal data to this application**

3.9. Confirmation of information

Obligatory box to tick:

- I accept that the health data body will compile the statistics and I will have no access to the data used to form the statistics.

Before this application is processed, you as the applicant must approve processing fees. To add information on the prices once available.

To submit your application, you need to confirm the following:*

- I am aware that a processing fee will be charged for processing my application. It will also apply in case of a cancelled request or negative decision.
- I am aware that data holder(s) may charge a fee for providing the data.
- I confirm that the information I have provided is correct.

[66] Here you can provide further information on any of the sections in your application. Indicate the number of section and the question to which your comment refers.

[67] If you have any other attachment that you deem relevant regarding the processing of your application and necessary for the Health Data Access Body to see, attach it here. Describe its relevance in the text field above.

Annex 2: Common data application form (table)

Section	Type	Question	Mandatory
1. Selecting the country and database	instructions	*Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice.*	n/a
	dropdown menu	To which health data access body/bodies do you want to submit the application?	yes
2. Public information on the project	instructions	*The health data access bodies in the European Union are obliged to publish information on the data permits, requests and applications…*	n/a
	text field	Project name	yes
	text field	Project leader name (organisation, institution, private sector entity, or a natural person)	yes
	dropdown menu	Country of the project leader	yes
	dropdown menu	Purpose for which the data will be used	yes
	dropdown menu	The research focuses on the following objectives	no
	dropdown menu	Area of research	no
	text field	Description of the data you will use (Describe it on the level suitable to be published…	yes
	text field	Summary of the project (max. 500 characters) If, for some reason, the nature of your project…	yes
3. Applicant and contact person information	radio button	Are you applying for data on behalf of a public sector body or a European Union institution, body, office or agency? Yes/No	yes
	radio button	If yes: Are you applying for data for carrying out tasks enshrined in the mandate of your organisation/institution?	yes
	radio button	Legal person or natural person	yes
	text field	If legal person: Full name	yes
	text field	If legal person: Postal address (street name and number, zip code, city/town, country)	yes
	text field	If legal person: Business ID or similar	yes
	text field	Contact person: Full name	yes
	text field	Contact person: Job title (if related to the project and data processing)	no
	text field	Contact person: E-mail address	yes
	text field	Contact person: Phone number (including the country code)	yes
	text field	Contact person: What is the relationship between the contact person and the applicant? E.g. an employee applying for data on behalf of their organisation.	yes

Section	Type	Question	Mandatory
	text field	If natural person: Full name	yes
	text field	If natural person: Postal address (street name and number, zip code, city/town, country	yes
	text field	If natural person: Phone number (including the country code)	yes
4. Payment details	instructions	*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:*	n/a
	text field	Payer's full name	yes
	text field	Payer's postal address	yes
	text field	Payer's e-mail address	yes
	text field	Payer's phone number	yes
	radio button	Invoice type: paper/electronic	yes
	text field	Invoice reference	yes
	text field	If electronic invoice: E-invoice address (EDI or IBAN)	yes
	text field	If legal person: Operator ID	yes
	text field	If legal person: Name of the organisation	yes
	text field	If legal person: Business ID of the organisation	yes
	text field	If legal person: VAT number	yes
	text field	If legal person: Peppol code (if applicable)	no
5. Purpose of data use	instructions	*Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing*	n/a
	checkbox	Select the option corresponding to your purpose of data use	yes
	text field	Why are the data you are applying for needed for the indicated purpose of use? (Max. 1000 characters)	yes
	text field	What is the aim and topic of your project? (Max. 1000 characters)	yes
	text field	If a public sector/EU body: Specify the legal basis, for example the relevant legislation, which defines the tasks falling within your mandate and confirm that your planned use of the data is to facilitate such tasks	yes
	text field	If a public sector/EU body: Provide a link to the supporting documentation as evidence of the legal basis	yes
	attachment	If not research: Provide a summary of your plan for using the data. The summary must be a maximum of two pages long and written in one of the official EU languages	yes
	text field	Person responsible for data use: Full name	yes
	text field	Person responsible for data use: Job title	yes
	text field	Person responsible for data use: Affiliation	yes
	attachment	If research (option (e) is chosen): Provide a summary of your research plan. The summary must be a maximum of two pages long and written in one of the official EU languages	yes

Section	Type	Question	Mandatory
	text field	If research (option (e) is chosen): Person responsible for the research: Full name	yes
	text field	If research (option (e) is chosen): Person responsible for the research: Job title	yes
	text field	If research (option (e) is chosen): Person responsible for the research: Affiliation	yes
	dropdown menu	Select the format of the electronic health data to be made available: anonymised/pseudonymised	yes
	instructions	If pseudonymised: *I am aware that in order to apply for pseudonymised data, I must a) explain how I will comply with… b) assess ethical aspects of….*	n/a
	text field	If pseudonymised: Why do you need pseudonymised data for your project?	yes
6. Description of the dataset needed	instructions	*In this section, you need to provide a description of the requested dataset, clearly indicating...*	n/a
	text field	If you have been in contact with someone from the health data access body regarding the data you seek, list here the names and the e-mail addresses of this person	no
	text field	How will the data from different sources be linked? E.g. based on personal identification code. If some kind of other linkage method is used, describe that here	yes
6.1 Defining the extraction criteria for the study cohort	radio button	How is the study cohort formed? (1) The study cohort will be formed based on the criteria given below (2) The study cohort has already been formed (3) The study cohort will consist of these two: a new cohort formed based on the criteria given below and an already formed cohort (4) The study cohort will be the whole population of a country/countries indicated at the beginning of this form	yes
	text field	If 2nd option: Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed	yes
	radio button	If 2nd option: If you wish to use a study cohort based on your own previous survey study, has the study cohort been formed based on informed consents of study participants? Yes/No	yes
	radio button	If 2nd option; If yes: Does the informed consent cover the requested registry extractions?	yes
	attachment	If 2nd option; If yes: Attach the consent and information letter that you have sent to the study subjects. Do not attach forms that are filled in because they include personal data.	yes
	checkbox	If 2nd option; If yes: I confirm that the data permit has been granted for this research project	yes
	text field	If 2nd option; If yes: Issuer, date, validity period and the code/other identifying information of the permit decision for the study cohort	yes

Section	Type	Question	Mandatory
	attachment	If 2nd option; If yes: Attach a permit decision covering the extraction of the study cohort data in this section	yes
	text field	If 2nd option; If not: Describe how the study cohort was obtained and the reasons for the lack of data permit/consent	yes
	radio button	Have you provided information of the data use to the corresponding subjects? E.g. shared information of the data use on a project website. Yes/No	yes
	text field	If yes: How?	yes
	text field	If not: Why not?	yes
	text field	If 2nd OR 3rd option: Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed	yes
	text field	If 2nd OR 3rd option: Who will deliver the information on the study cohort to the health data access body? This can be the applicant or someone else. Full name, e-mail, phone number (including the country code). This person will receive instructions on how to deliver the data through the common EHDS portal.	yes
	text field	If 4th option: Provide arguments why you need data of a whole population/whole populations	yes
	instructions	*Make sure to define the formation of the study cohort clearly enough and delimit the cohort size according to the intended use. Pay special attention...*	n/a
	radio button	Size of the study cohort	yes
	radio button	Continuation of the above question: This is an estimation of the size of the study cohort / This is the exact size of the study cohort	yes
	text field	Why do you need a study cohort of this size for your project?	yes
	dropdown menu	From which country/countries do you seek data?	yes
	text field	If you do not seek data from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data	no
	information	The requirements related to the ethical review to be shown here, based on the country (and region) selection	n/a
	dropdown menu	From which data holder(s) will the data be extracted?	yes
	information	The required attachments to be listed here, based on the country (and region) selection and/or the data holder(s)	n/a
	dropdown menu	From which database(s) or registry/registries will the data be extracted?	yes
	dropdown menu	From which dataset(s) or register(s) will the data be extracted?	yes
	text field	If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no

Section	Type	Question	Mandatory
	text field	For which time period(s) will the datasets be extracted?	yes
	dropdown menu	Extraction method: random sample / all the people fulfilling the criteria / other sample	yes
	text field	If 'other sample': Describe the sampling method	yes
	text field	If 'random sample' or 'other sample': Sample size	yes
	text field	Describe the inclusion criteria for study cohort extraction	yes
	text field	Describe the potential exclusion criteria for study cohort extraction	no
	dropdown menu	How often does the data need to be extracted? once / multiple times	yes
	dropdown menu	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the study cohort extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the study cohort data be extracted?	no
6.2 Defining the extraction criteria for controls	radio button	Will controls be extracted for the study cohort defined above? Yes/No	yes
	information	If not, no further questions regarding controls	n/a
	radio button	Will same data as for the study cohort be extracted for controls? Yes/No	yes
	dropdown menu	If not: From which country will the data for controls be extracted?	yes
	text field	If not: If you do not seek data for controls from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data	no
	dropdown menu	If not: From which data holder(s) will the data for controls be extracted?	yes
	dropdown menu	If not: From which database(s)/registry/registries will the data for controls be extracted?	yes
	dropdown menu	If not: From which dataset(s)/register(s) will the data for controls be extracted?	yes
	text field	If not: If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no
	text field	If not: For which time period(s) will the datasets be extracted?	yes
	text field	If not: Specify the extraction criteria for controls, e.g. matching criteria	yes
	text field	Size of the control group	yes
	radio button	Continuation of the above question: This is an estimation of the size of the group of controls / This is the exact size of the group of controls	yes

Section	Type	Question	Mandatory
	text field	How many controls are extracted per person belonging to the study cohort?	yes
	text field	Describe the inclusion criteria for controls' extraction	yes
	text field	Describe the potential exclusion criteria for controls' extraction	no
	text field	If the group of controls has been formed based on a previously issued permit, list here the issuer of the permit decision, date, validity period and permit number	no
	radio button	Will the data for controls be extracted at the same time and in the same order as the data for the study cohort? Yes/No	yes
	information	If yes, no further questions in this 'times and order section'	n/a
	radio button	If not: How often does the data need to be extracted? once / multiple times	yes
	dropdown menu	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the controls' data be extracted?	no
6.3 Defining the extraction criteria for relatives	radio button	Will relatives be extracted for the study cohort? Yes/No	yes
	radio button	Will same data as for the study cohort be extracted for relatives? Yes/No	yes
	dropdown menu	If not: From which data holder(s) will the data for relatives be extracted?	yes
	dropdown menu	If not: From which database(s)/registry/registries will the data for relatives be extracted?	yes
	dropdown menu	If not: From which dataset(s)/register(s) will the data for relatives be extracted?	yes
	text field	If not: If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no
	text field	If not: For which time period(s) will the datasets be extracted?	yes
	text field	If not: Define the relationship of the relatives to the person belonging to the study cohort (e.g. grandparents, biological parents, mother)	yes
	text field	If the group of relatives have been formed on the basis of a previously issued permit(s), list here the issuer of the permit decision, date, validity period and any identifying information	no
	text field	Size of the group of relatives	yes
	radio button	Continuation of the above question: This is an estimation of the size of the group of relatives / the exact size of the group of relatives	yes

Section	Type	Question	Mandatory
	radio button	Will the data for relatives be extracted at the same time and in the same order as the data for the study cohort? Yes/No	yes
	radio button	If not: How often does the data need to be extracted? once / multiple times	yes
	radio button	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the relatives' data be extracted?	no
7. Other data to be combined	instructions	*It is possible to combine other data, such as data in your possession or data obtained from elsewhere, with the data applied for with…*	n/a
	radio button	Will the data you are applying for be combined with data you have already obtained or data from other sources? Yes/No	yes
	text field	If yes: List the other data to be combined and the sources of this data: Country/countries	yes
	text field	Continuation of the question above: Data holder(s)	yes
	text field	Continuation of the question above: Database(s)/Registry/Registries	yes
	text field	Continuation of the question above: Dataset(s)/Register/Registers	yes
	text field	If yes: Provide information on data to be combined and the planned combination method	yes
	instructions	*List here any other data permits issued for the same project. The permits must be valid at the time data are processed.*	n/a
	text field	Other permits: issuer, date of issue, expiry date, identification information	yes
	attachment	If the datasets involve permits issued by other parties or they have been collected with consent, attach the permit documents here	no
	radio button	Do you have other pending permit applications? Yes/No	yes
	text field	If yes: Date of submitting the application, issuer, identification code	yes
8. Data processing, data protection and safeguards to prevent unauthorised use of data	instructions	*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.*	n/a
	text field	List here all the technical requirements you have for the secure processing environment	yes
	text field	If you already know which processing environment you want to use, what is its name and where is it located?	no
	instructions	*The health data access body will deliver the data once your application is processed if you are granted a data permit. The health data…*	n/a

Section	Type	Question	Mandatory
	radio button	When do you need the data? As soon as possible after this application has been processed / Later, when?	yes
	date	If 'later, when': Date	yes
	text field	If a public sector or EU body applicant: Provide information on the period for which the data can be accessed	yes
	text field	If a public sector or EU body applicant: What is the frequency of that access or the frequency of the data updates?	yes
	date–date	Any other applicant: What are the estimated start and end dates of the period during which the electronic health data is needed for processing?	yes
	date–date	If you need to store the data after processing, indicate here the period of inactive data storage	no
	radio button	Will the data be transferred outside the EU or the EEA? Yes/No	yes
	dropdown menu	If yes: In which country/countries outside the EU/EEA will the data be processed?	yes
	dropdown menu	If yes: Why will the data be transferred outside the EU or the EEA? -options from GDPR-	yes
	radio button	What is the legal basis for transferring the data outside the EU or EEA?	yes
	dropdown menu	If yes; If transfer reason referring to GDPR Art. 46: These safeguards are provided by:	yes
	dropdown menu	If yes; If 'Other exceptional legal basis (in absence of appropriate safeguards pursuant to article 46)': -to choose an option-	yes
	text field	Which organisation(s) or individual will be the controller of the data to be formed based on this application?	yes
	text field	If any other applicant than an EU body: How do you comply with the principle of data minimisation (EU General Data Protection Regulation) when processing the data?	yes
	text field	If an EU body applicant: How do you comply with the principle of data minimisation (EU Data Protection Regulation) when processing the data?	yes
	checkbox	To proceed with this application, you need to confirm the following statements: -data protection and security related statements-	yes
	instructions	*Only the people mentioned in the data permit will be granted access to process the data in the secure processing environment.*	n/a
	text field	List the full names, affiliations and e-mail addresses of all the people who will be processing the data	yes
	instructions	*If a natural person or a public sector authority is applying for data in pseudonymised format: Lawfulness of processing, GDPR Art. 6(1)*	n/a
	dropdown menu	What is the legal basis for processing the personal data that you are applying for with this application form? GDPR Art. 6(1) (e) / (f) / Other, which?	yes

Section	Type	Question	Mandatory
	dropdown menu	If the applicant has filled in section 7: What is the legal basis for processing the other data that you will combine with data applied for in this application (section 7)? GDPR Art. 6(1) (e) / (f) / Other, which?	yes
	instructions	*If a European Union institution, body, office or agency is applying for data in pseudonymised format: Lawfulness or processing, EU DPR Art. 5(1) (a) / Other, which?*	yes
	dropdown menu	What is the legal basis for processing the personal data that you are applying for with this application form? EU DPR Art. 5(1) (a) / Other, which?	yes
	dropdown menu	If the applicant has filled in section 7: What is the legal basis for processing the other data that you will combine with data applied for in this application (section 7)? GDPR Art. 6(1) (e) / (f) / Other, which?	yes
	attachment	If research: If your research requires a research permit from your affiliation organisation, attach the research permit	no
9. Additional information	text field	Further information or any additional notes	no
	attachment	An additional attachment. Do not attach health or personal data to this application.	no
10. Confirmation of information	instructions	*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.*	n/a
	checkbox	I am aware that a processing fee will be charged for processing my application. It will also apply in case of a cancelled request or negative decision.	yes
	checkbox	I am aware that data holder(s) may charge a fee.	yes
	checkbox	I confirm that the information I have provided is correct.	yes

Annex 3: Data request (table)

Section	Type	Question	Mandatory
1. Selecting the country and database	instructions	*Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice.*	n/a
	dropdown menu	To which health data access body/bodies do you want to submit the application?	yes
2. Public information on the project	instructions	*The health data access bodies in the European Union are obliged to publish information on the data permits, requests and applications…*	n/a
	text field	Project name	yes
	text field	Project leader name (organisation, institution, private sector entity, or a natural person)	yes
	dropdown menu	Country of the project leader	yes
	dropdown menu	Purpose for which the data will be used	yes
	dropdown menu	The research focuses on the following objectives	no
	dropdown menu	Area of research	no
	text field	Description of the data you will use (Describe it on the level suitable to be published…	yes
	text field	Summary of the project (max. 500 characters) If, for some reason, the nature of your project…	yes
3. Applicant and contact person information	radio button	Are you applying for data on behalf of a public sector body or a European Union institution, body, office or agency? Yes/No	yes
	radio button	If yes: Are you applying for data for carrying out tasks enshrined in the mandate of your organisation/institution?	yes
	radio button	Legal person or natural person	yes
	text field	If legal person: Full name	yes
	text field	If legal person: Postal address (street name and number, zip code, city/town, country)	yes
	text field	If legal person: Business ID or similar	yes
	text field	Contact person: Full name	yes
	text field	Contact person: Job title (if related to the project and data processing)	no

Section	Type	Question	Mandatory
	text field	Contact person: E-mail address	yes
	text field	Contact person: Phone number (including the country code)	yes
	text field	Contact person: What is the relationship between the contact person and the applicant? E.g. an employee applying for data on behalf of their organisation.	yes
	text field	If natural person: Full name	yes
	text field	If natural person: Postal address (street name and number, zip code, city/town, country	yes
	text field	If natural person: Phone number (including the country code)	yes
4. Payment details	instructions	*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:*	n/a
	text field	Payer's full name	yes
	text field	Payer's postal address	yes
	text field	Payer's e-mail address	yes
	text field	Payer's phone number	yes
	radio button	Invoice type: paper/electronic	yes
	text field	Invoice reference	yes
	text field	If electronic invoice: E-invoice address (EDI or IBAN)	yes
	text field	If legal person: Operator ID	yes
	text field	If legal person: Name of the organisation	yes
	text field	If legal person: Business ID of the organisation	yes
	text field	If legal person: VAT number	yes
	text field	If legal person: Peppol code (if applicable)	no
5. Purpose of data use	instructions	*Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing*	n/a

Section	Type	Question	Mandatory
	checkbox	Select the option corresponding to your purpose of data use	yes
	text field	Why are the data you are applying for needed for the indicated purpose of use? (Max. 1000 characters)	yes
	text field	What is the aim and topic of your project? (Max. 1000 characters)	yes
	text field	If a public sector/EU body: Specify the legal basis, for example the relevant legislation, which defines the tasks falling within your mandate and confirm that your planned use of the data is to facilitate such tasks	yes
	text field	If a public sector/EU body: Provide a link to the supporting documentation as evidence of the legal basis	yes
	attachment	If not research: Provide a summary of your plan for using the data. The summary must be a maximum of two pages long and written in one of the official EU languages	yes
	text field	Person responsible for data use: Full name	yes
	text field	Person responsible for data use: Job title	yes
	text field	Person responsible for data use: Affiliation	yes
	attachment	If research (option (e) is chosen): Provide a summary of your research plan. The summary must be a maximum of two pages long and written in one of the official EU languages	yes
	text field	If research (option (e) is chosen): Person responsible for the research: Full name	yes
	text field	If research (option (e) is chosen): Person responsible for the research: Job title	yes
	text field	If research (option (e) is chosen): Person responsible for the research: Affiliation	yes
	dropdown menu	Select the format of the electronic health data to be made available: anonymised/pseudonymised	yes
	instructions	If pseudonymised: *I am aware that in order to apply for pseudonymised data, I must a) explain how I will comply with… b) assess ethical aspects of….*	n/a
	text field	If pseudonymised: Why do you need pseudonymised data for your project?	yes
6. Description of the dataset needed	instructions	*In this section, you need to provide a description of the requested dataset, clearly indicating...*	n/a
	text field	If you have been in contact with someone from the health data access body regarding the data you seek, list here the names and the e-mail addresses of this person	no

Section	Type	Question	Mandatory
	text field	How will the data from different sources be linked? E.g. based on personal identification code. If some kind of other linkage method is used, describe that here	yes
6.1 Defining the extraction criteria for the study cohort	radio button	How is the study cohort formed? (1) The study cohort will be formed based on the criteria given below (2) The study cohort has already been formed (3) The study cohort will consist of these two: a new cohort formed based on the criteria given below and an already formed cohort (4) The study cohort will be the whole population of a country/countries indicated at the beginning of this form	yes
	text field	If 2nd option: Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed	yes
	radio button	If 2nd option: If you wish to use a study cohort based on your own previous survey study, has the study cohort been formed based on informed consents of study participants? Yes/No	yes
	radio button	If 2nd option; If yes: Does the informed consent cover the requested registry extractions?	yes
	attachment	If 2nd option; If yes: Attach the consent and information letter that you have sent to the study subjects. Do not attach forms that are filled in because they include personal data.	yes
	checkbox	If 2nd option; If yes: I confirm that the data permit has been granted for this research project	yes
	text field	If 2nd option; If yes: Issuer, date, validity period and the code/other identifying information of the permit decision for the study cohort	yes
	attachment	If 2nd option; If yes: Attach a permit decision covering the extraction of the study cohort data in this section	yes
	text field	If 2nd option; If not: Describe how the study cohort was obtained and the reasons for the lack of data permit/consent	yes
	radio button	Have you provided information of the data use to the corresponding subjects? E.g. shared information of the data use on a project website. Yes/No	yes
	text field	If yes: How?	yes
	text field	If not: Why not?	yes
	text field	If 2nd OR 3rd option: Provide details on how and based on what legal documents (e.g. permits and/or informed consent) the study cohort has been formed	yes
	text field	If 2nd OR 3rd option: Who will deliver the information on the study cohort to the health data access body? This can be the applicant or someone else. Full name, e-mail, phone number (including the country	yes

Section	Type	Question	Mandatory
		code). This person will receive instructions on how to deliver the data through the common EHDS portal.	
	text field	If 4th option: Provide arguments why you need data of a whole population/whole populations	yes
	instructions	*Make sure to define the formation of the study cohort clearly enough and delimit the cohort size according to the intended use. Pay special attention...*	n/a
	radio button	Size of the study cohort	yes
	radio button	Continuation of the above question: This is an estimation of the size of the study cohort / This is the exact size of the study cohort	yes
	text field	Why do you need a study cohort of this size for your project?	yes
	dropdown menu	From which country/countries do you seek data?	yes
	text field	If you do not seek data from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data	no
	information	The requirements related to the ethical review to be shown here, based on the country (and region) selection	n/a
	dropdown menu	From which data holder(s) will the data be extracted?	yes
	information	The required attachments to be listed here, based on the country (and region) selection and/or the data holder(s)	n/a
	dropdown menu	From which database(s) or registry/registries will the data be extracted?	yes
	dropdown menu	From which dataset(s) or register(s) will the data be extracted?	yes
	text field	If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no
	text field	For which time period(s) will the datasets be extracted?	yes
	dropdown menu	Extraction method: random sample / all the people fulfilling the criteria / other sample	yes
	text field	If 'other sample': Describe the sampling method	yes
	text field	If 'random sample' or 'other sample': Sample size	yes
	text field	Describe the inclusion criteria for study cohort extraction	yes
	text field	Describe the potential exclusion criteria for study cohort extraction	no
	dropdown menu	How often does the data need to be extracted? once / multiple times	yes

Section	Type	Question	Mandatory
	dropdown menu	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the study cohort extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the study cohort data be extracted?	no
6.2 Defining the extraction criteria for controls	radio button	Will controls be extracted for the study cohort defined above? Yes/No	yes
	information	If not, no further questions regarding controls	n/a
	radio button	Will same data as for the study cohort be extracted for controls? Yes/No	yes
	dropdown menu	If not: From which country will the data for controls be extracted?	yes
	text field	If not: If you do not seek data for controls from the whole country, from which region(s) and/or city/cities and/or municipality/municipalities do you seek data	no
	dropdown menu	If not: From which data holder(s) will the data for controls be extracted?	yes
	dropdown menu	If not: From which database(s)/registry/registries will the data for controls be extracted?	yes
	dropdown menu	If not: From which dataset(s)/register(s) will the data for controls be extracted?	yes
	text field	If not: If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no
	text field	If not: For which time period(s) will the datasets be extracted?	yes
	text field	If not: Specify the extraction criteria for controls, e.g. matching criteria	yes
	text field	Size of the control group	yes
	radio button	Continuation of the above question: This is an estimation of the size of the group of controls / This is the exact size of the group of controls	yes
	text field	How many controls are extracted per person belonging to the study cohort?	yes
	text field	Describe the inclusion criteria for controls' extraction	yes
	text field	Describe the potential exclusion criteria for controls' extraction	no

Section	Type	Question	Mandatory
	text field	If the group of controls has been formed based on a previously issued permit, list here the issuer of the permit decision, date, validity period and permit number	no
	radio button	Will the data for controls be extracted at the same time and in the same order as the data for the study cohort? Yes/No	yes
	information	If yes, no further questions in this 'times and order section'	n/a
	radio button	If not: How often does the data need to be extracted? once / multiple times	yes
	dropdown menu	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the controls' data be extracted?	no
6.3 Defining the extraction criteria for relatives	radio button	Will relatives be extracted for the study cohort? Yes/No	yes
	radio button	Will same data as for the study cohort be extracted for relatives? Yes/No	yes
	dropdown menu	If not: From which data holder(s) will the data for relatives be extracted?	yes
	dropdown menu	If not: From which database(s)/registry/registries will the data for relatives be extracted?	yes
	dropdown menu	If not: From which dataset(s)/register(s) will the data for relatives be extracted?	yes
	text field	If not: If the information is available, list the variables to be used in the data extraction. Use the exact terms...	no
	text field	If not: For which time period(s) will the datasets be extracted?	yes
	text field	If not: Define the relationship of the relatives to the person belonging to the study cohort (e.g. grandparents, biological parents, mother)	yes
	text field	If the group of relatives have been formed on the basis of a previously issued permit(s), list here the issuer of the permit decision, date, validity period and any identifying information	no
	text field	Size of the group of relatives	yes
	radio button	Continuation of the above question: This is an estimation of the size of the group of relatives / the exact size of the group of relatives	yes
	radio button	Will the data for relatives be extracted at the same time and in the same order as the data for the study cohort? Yes/No	yes

Section	Type	Question	Mandatory
	radio button	If not: How often does the data need to be extracted? once / multiple times	yes
	radio button	If multiple times: The data needs to be extracted every: year / half a year / quarter / other, specify	yes
	instructions	*If you want the data to be extracted multiple times over a certain period of time, note that the definitions and the data collection method may change during the review period in some cases.*	n/a
	text field	Provide more information on the extracting periods/times	yes
	text field	If it affects the results of the data extraction, in which order will the relatives' data be extracted?	no
7. Other data to be combined	instructions	*It is possible to combine other data, such as data in your possession or data obtained from elsewhere, with the data applied for with…*	n/a
	radio button	Will the data you are applying for be combined with data you have already obtained or data from other sources? Yes/No	yes
	text field	If yes: List the other data to be combined and the sources of this data: Country/countries	yes
	text field	Continuation of the question above: Data holder(s)	yes
	text field	Continuation of the question above: Database(s)/Registry/Registries	yes
	text field	Continuation of the question above: Dataset(s)/Register/Registers	yes
	text field	If yes: Provide information on data to be combined and the planned combination method	yes
	instructions	*List here any other data permits issued for the same project. The permits must be valid at the time data are processed.*	n/a
	text field	Other permits: issuer, date of issue, expiry date, identification information	yes
	attachment	If the datasets involve permits issued by other parties or they have been collected with consent, attach the permit documents here	no
	radio button	Do you have other pending permit applications? Yes/No	yes
	text field	If yes: Date of submitting the application, issuer, identification code	yes
8. Data processing, data protection and safeguards to prevent	instructions	*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.*	n/a
	text field	List here all the technical requirements you have for the secure processing environment	yes
	text field	If you already know which processing environment you want to use, what is its name and where is it located?	no

Section	Type	Question	Mandatory
unauthorised use of data	instructions	*The health data access body will deliver the data once your application is processed if you are granted a data permit. The health data…*	n/a
	radio button	When do you need the data? As soon as possible after this application has been processed / Later, when?	yes
	date	If 'later, when': Date	yes
	text field	If a public sector or EU body applicant: Provide information on the period for which the data can be accessed	yes
	text field	If a public sector or EU body applicant: What is the frequency of that access or the frequency of the data updates?	yes
	date–date	Any other applicant: What are the estimated start and end dates of the period during which the electronic health data is needed for processing?	yes
	date–date	If you need to store the data after processing, indicate here the period of inactive data storage	no
	radio button	Will the data be transferred outside the EU or the EEA? Yes/No	yes
	dropdown menu	If yes: In which country/countries outside the EU/EEA will the data be processed?	yes
	dropdown menu	If yes: Why will the data be transferred outside the EU or the EEA? -options from GDPR-	yes
	radio button	What is the legal basis for transferring the data outside the EU or EEA?	yes
	dropdown menu	If yes; If transfer reason referring to GDPR Art. 46: These safeguards are provided by:	yes
	dropdown menu	If yes; If 'Other exceptional legal basis (in absence of appropriate safeguards pursuant to article 46)': -to choose an option-	yes
	text field	Which organisation(s) or individual will be the controller of the data to be formed based on this application?	yes
	text field	If any other applicant than an EU body: How do you comply with the principle of data minimisation (EU General Data Protection Regulation) when processing the data?	yes
	text field	If an EU body applicant: How do you comply with the principle of data minimisation (EU Data Protection Regulation) when processing the data?	yes
	checkbox	To proceed with this application, you need to confirm the following statements: -data protection and security related statements-	yes
	instructions	*Only the people mentioned in the data permit will be granted access to process the data in the secure processing environment.*	n/a
	text field	List the full names, affiliations and e-mail addresses of all the people who will be processing the data	yes
	instructions	*If a natural person or a public sector authority is applying for data in pseudonymised format: Lawfulness of processing, GDPR Art. 6(1)*	n/a

Section	Type	Question	Mandatory
	dropdown menu	What is the legal basis for processing the personal data that you are applying for with this application form? GDPR Art. 6(1) (e) / (f) / Other, which?	yes
	dropdown menu	If the applicant has filled in section 7: What is the legal basis for processing the other data that you will combine with data applied for in this application (section 7)? GDPR Art. 6(1) (e) / (f) / Other, which?	yes
	instructions	*If a European Union institution, body, office or agency is applying for data in pseudonymised format: Lawfulness or processing, EU DPR Art. 5(1) (a) / Other, which?*	yes
	dropdown menu	What is the legal basis for processing the personal data that you are applying for with this application form? EU DPR Art. 5(1) (a) / Other, which?	yes
	dropdown menu	If the applicant has filled in section 7: What is the legal basis for processing the other data that you will combine with data applied for in this application (section 7)? GDPR Art. 6(1) (e) / (f) / Other, which?	yes
	attachment	If research: If your research requires a research permit from your affiliation organisation, attach the research permit	no
9. Additional information	text field	Further information or any additional notes	no
	attachment	An additional attachment. Do not attach health or personal data to this application.	no
10. Confirmation of information	instructions	*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.*	n/a
	checkbox	I am aware that a processing fee will be charged for processing my application. It will also apply in case of a cancelled request or negative decision.	yes
	checkbox	I am aware that data holder(s) may charge a fee.	yes
	checkbox	I confirm that the information I have provided is correct.	yes

References

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