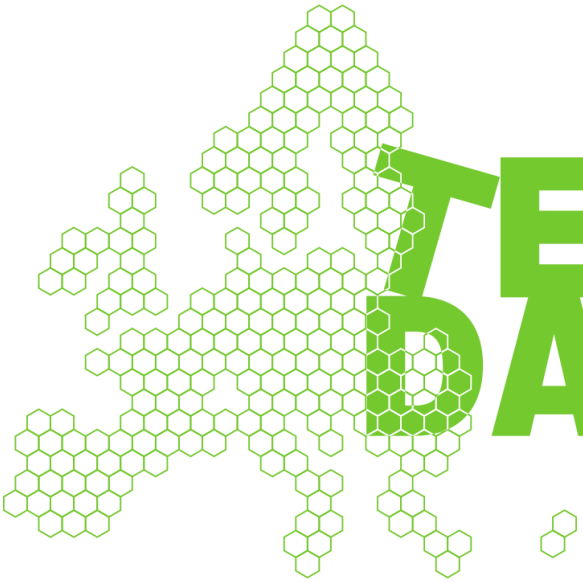

Towards European Health Data Space

Milestone 5.5

Guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data

31 March 2022

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0 Document info

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Contents

1. Executive Summary

In the interest of developing and sharing best practices for peer-to-peer and cross-border partnerships for the secondary use of health data across Europe, this document proposes generic guidelines to be shared and discussed with European stakeholders.

This **Guideline document for a peer-to- peer and cross-border partnership for the secondary use of health data** proposes 6 major steps to follow to initiate a bi- or multilateral partnership agreement between structures wishing to share health data for secondary use.

Although the major steps of this framework are common to most partnership forms, particular attention is provided to *data sharing projects* for which no widely accepted framework exists today. In the framework of the future European Health Data Space, data sharing partnerships for the secondary use of health data are crucial to open up national data assets with the objective to improve European population health and foster better collaboration around research and innovation in the field. Guidelines, by enabling a common understanding of the types and steps to establish such collaborations, will facilitate the emergence of new partnerships.

While respective national contexts and interests might differ and affect the type of partnership chosen, this document is a first step towards sharing best practices for cross-border collaboration around health data.

2. Context

This document is prepared as part of TEHDAS Joint Action Work Package 5 “Sharing Data for Health” task 5.3 “Defining best practices for EU-cross border sharing of personal health data”. One of the main goals of this task is the establishment of a framework of a bi- or multilateral partnership agreement between structures responsible for the secondary use of health data.

The following document presents the **Milestone 5.5: Guideline document for a peer-to- peer and cross-border partnership for the secondary use of health data**.

TEHDAS is conducted by 25 European countries and coordinated by the Finnish Innovation Fund, Sitra. The project aims to develop concepts for the secondary use of health data in Europe.

TEHDAS boosts knowledge-based decision-making, sustainable healthcare and smart innovations by developing common practices for the cross-border sharing and wider use of health data in Europe. Besides, TEHDAS aims to enhance the use of health data to facilitate better policymaking, to enable better environment for research, innovation and business, and to provide better healthcare for citizens.

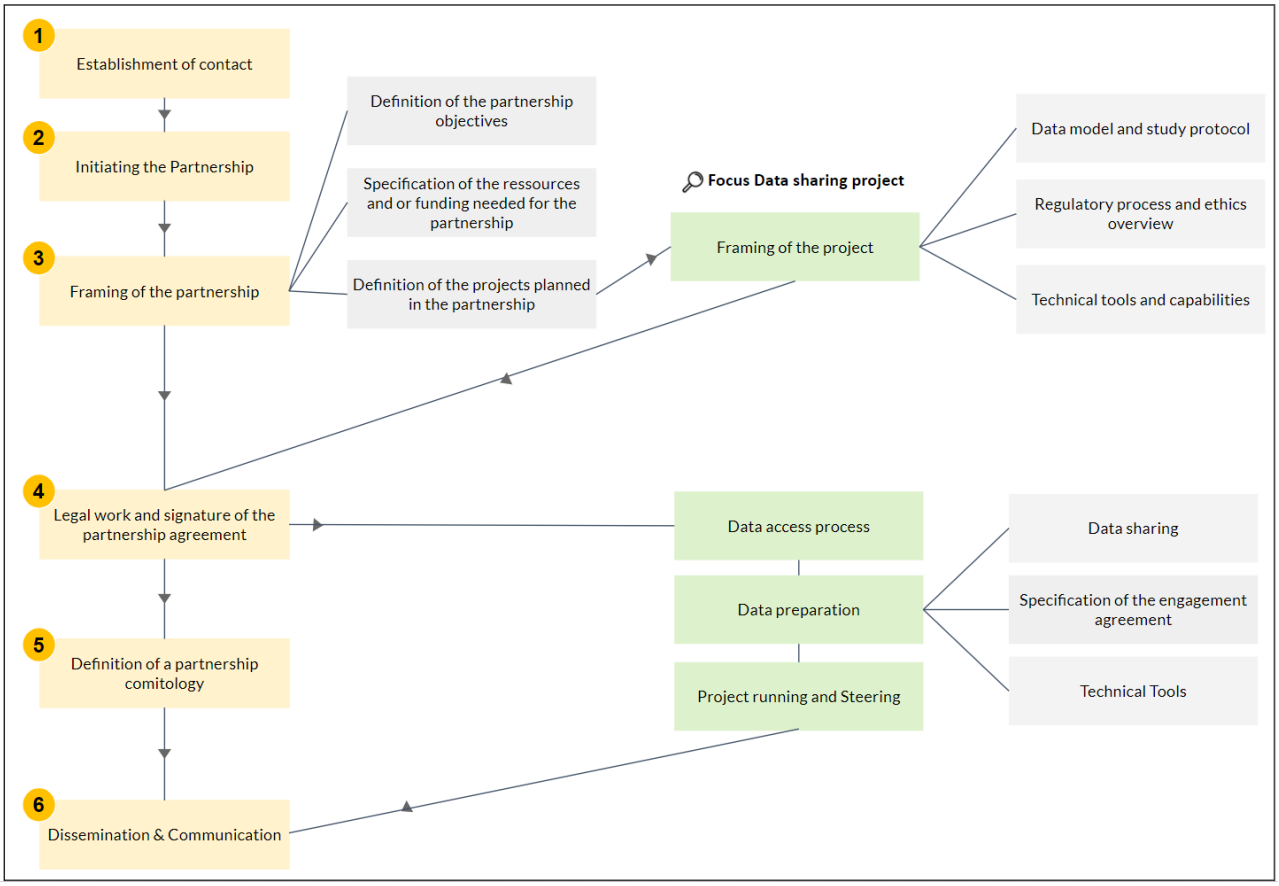
3. Guidelines for a peer-to-peer and cross-border partnership for the secondary use of health data

EU countries face similar challenges from the increasing incidence of diseases related to lifestyle and changing demography, to increasing unsustainable healthcare costs, and most recently the COVID-19 public health crisis. These complex problems are better solved using the full capacity of the European research community and it makes health a cross-border issue. Large-scale collaborations in Europe build critical mass, increase competitive advantage, and ensure greater international resilience, impact and visibility. They can generate more and better health data, decrease the risk of bias in data, create new potential for linkage of health and non-health data, promote data enrichment, support deployment of artificial intelligence, and enable IT-improvements towards more timely and real time assessments.

This guideline section describes all the typical phases and steps involved in a situation in which a cross-border partnership for the secondary use of health data is established.

The 6 major steps illustrated in the figure below will be detailed in the text that follows with a focus on a particular example around a cross-border data sharing partnership.

Figure 1: Major steps for the establishment of a cross-border partnership for the secondary use of health data



STEP 1: Establishing contact between prospective partners

Data sharing on a European scale is fundamental for research, innovation, policy-making and regulatory purposes. For this purpose, national health data platforms are strongly encouraged to work together through cross-border partnerships.
National health data platforms have each developed a network of local and international partners allowing them to share their experiences, enrich their expertise and develop common best practices. Consequently, prospective partners often stem from their own networks, including the projects they might be already involved in.

STEP 2: Initiating the partnership

Once prospective partners start a dialogue allowing them to identify a mutual interest for collaboration, the partnership can be initiated. This step is dedicated to further discussing interests for collaboration in order to brush the broad strokes of the partnership before the framing phase.

This phase can translate into regular meetings, working or brainstorming sessions. During this phase, each prospective partner is invited to reflect on the resources to be dedicated to the partnership at hand and to propose a first vision for the collaboration.

STEP 3: Framing the partnership

Framing a project is a key step before the beginning of the project. The framing phase is therefore very important in order to carry out the project in optimal conditions. Among other things, the framing will allow you to define the context, the goals and the objectives of the partnership. It also aims to identify the added value of the partnership and help align the needs. It is also an opportunity to identify the means and resources necessary to implement the project.
The framing phase could be conducted following 3 sub steps:

3.1. Defining the partnership objectives

Once contact is established amongst prospective partners, stakeholders involved must define together the object and purpose of their partnership.
In the case of a first contact, each of the partners present their respective fields of intervention and activities. Potential collaborative activities are thus identified as a result of these discussions. In the event where a specific project collaboration has been previously identified, the object of the collaboration is already defined beforehand, and it is therefore sufficient to refine it further.
The expected benefits and results should also be defined at this stage.

3.2. Specifying the resources and/or funding needed for the partnership

Based on the objectives jointly defined in the previous step, parties to the partnership need to evaluate the resources and/or funding required to support their collaborative project(s). As such, partners need first to define a sustainable financial model based on which of the following forms the partnership will take:

- The partnership requires mobilisation of human resources only
- The partnership requires mobilisation of funding from one or both partners
- The partnership requires both human and financial resources from partners.

The required funds may cover the following costs in the case of a cross-border data sharing project:

- Data access costs
- Infrastructure and technical costs
- Running and operating costs
- Personnel costs.

3.3. Defining the projects planned in the partnership

Partnership projects may take various forms. For instance, it can take the form of a collaborative partnership to share experiences, best practices and exchange expertise through joint events, but it can also translate into an actual scientific collaboration which will mobilise specific technical skills such as the conduct of a cross-border study requiring data sharing between multiple countries.
In the following section, the focus will be on the latter example in order to detail the set-up process for this type of project which stands out in comparison with the standard process for other types of

partnership projects.

Focus on Data sharing project

In the case of data sharing projects, one of the major aspects to define is the intended data sharing scope under the partnership. For example:

- Unilateral access to one of the other national data platforms involved
- Mutual Access to all national platforms involved
- Cross-border transfer of health data between platforms
- Cross-border access to health data without data transfer
- Query on the metadata catalogue
- Cross-border data analysis without seeing the data (e.g., request for a statistical analysis).

This will significantly impact the rest of the process, especially the regulatory one.

I- Definition of the data model and study protocol

Defining a data model might include taking into account the following aspects. *This list is however not exhaustive.*

- Description of the data required for the partnership project *(e.g., type and content of the desired data, target population, data period (historical depth), estimated volume of data)*
- Specification of the data sources and availability:
  - Whether the database is existing or to be built; if existing, specify the origin of the data sources and the producing entity for each data provider participating in the partnership project
  - The completeness of the database with respect to the needs and the target population
  - Whether the data are in the right format, annotated.
- If linkage of data is planned, specification of the linkage strategy including data sources and linkage variables
- Description of the data sharing model as defined above.

II- Regulatory process and ethics overview

Based on the established data sharing model in the partnership, the regulatory procedures applicable for each of the partners should be identified. Indeed, the data authorisation process and associated timeline can differ significantly from one country to another.
The partners should provide an overview of the regulatory process in order to identify all necessary regulatory steps to be taken by partners to share health data.
In most cases, there are 3 main questions that should be answered through the identification of the applicable regulatory process:

4. *Which data permit authority is competent to grant authorisation to access data?*
5. *Which procedure to follow regarding the data access authorisation?*
6. *Which essential elements must be taken into account in the application?*
7. *Is an ethical assessment required?*
8. *Is there a cost for the regulatory process?*

The data request procedure can differ depending on the country and the type of data holders involved. Most health data platforms use an electronic application system to streamline the data request applications.
Depending on the partners' respective practices, time to access data and technical considerations may go from 1 to 6 months (or more for some countries).
During this phase, the feasibility of the project is evaluated on the regulatory aspect.
The platform or structure responsible for the regulatory procedure takes its decision and in the case of a favourable response, a data permit is granted to the entities to access and possibly share the data.

NB: Partners to the agreement evolving in a decentralised national system might need to plan for a preliminary contractualisation phase in order to onboard data holders at the national level.

III- Definition of the technical tools and capabilities *(can be done in parallel with II)*

This step is important in order to define what are the functional and technical requirements and specifications needed to support the data sharing project.

For that, partners should for example:

- Describe the data processing plan: indicate the tool(s) (development framework, software, etc.) that will be used to analyse the data in the study; describe these tools with respect to the research question posed and the data available.
- Detail the mathematical or algorithmic methods (statistics, inference, modelling, machine learning, etc.) that will be used.
- Indicate the tools / technical capabilities of each of the participating infrastructures.

STEP 4: Legal work and signature of the partnership agreement

There are several types of legal partnership agreements. The most appropriate agreement form strongly depends on the nature of the partnership that will be concluded between the different parties.

Below is a list of possible types of legal partnership agreements. This list is not exhaustive. In practice, there is a large variety of possible forms of partnership agreements.

- **Data Sharing Agreement (DSA)**[1]
  A Data Sharing Agreement (DSA) could be defined as an agreement between two or more legal entities (or individuals) concerning the sharing of data or information of any kind between these legal entities (or individuals). The sharing of data could take many different forms depending on the specific needs of the parties such as for example:
    - Simple reciprocal exchange of data
    - One entity making data available to another entity or several entities
    - Several entities pooling data together and making it available for another entity

  The type of data shared could be also different depending on the objective of the sharing process agreement.

  The DSA should be in line and comply with the applicable (national) laws and regulations concerning the formation and execution of an agreement, notably relating to the activity of data sharing.
  As part of the DSA, parties could also agree on details related to specific obligations connected to the sharing of data such as time of disclosure, on the accuracy and completeness of data, obligations of the receiving party to manage the data according to specific rules and to apply

[1] Big Data & Issues & Opportunities: Data Sharing Agreements

certain security measures to protect the data, right of or prohibition to the receiving party to transfer onward/disclose the data to a third party, ownership of the data and intellectual property rights, payment of any consideration for the sharing of data, confidentiality obligations, audit of the receiving party by the disclosing party or by the authorities, warranties on the power to disclose and receive data, duration of the agreement, etc.

- **Memorandum of Understanding (MoU)**

A memorandum of understanding (MoU) is a written agreement between parties that intend to align themselves on common collaborative projects and agree to proceed with their mutual goals.
This type of agreement can be bilateral (between two parties) or multilateral (between more than two parties).
An MoU indicates that the parties have reached an understanding and are ready to move forward. Though an MoU is less formal than a legal contract.

- **Memorandum of Agreement (MoA)[2]**

A Memorandum of Agreement (MoA) is a written document describing a cooperative relationship between two parties wishing to work together on a project or to meet an agreed-upon objective. A MoA serves as a legal document and describes the terms and details of the partnership agreement.
A MOA is more formal than an MoU. Organisations can use a MoA to establish and outline collaborative agreements, including service partnerships or agreements to provide technical assistance and training.

🔎 *NB : Memorandum of Understanding (MoU) are used for simple common-cause agreements which are not legally binding. MoAs, on the other hand, establish common legal terms that establish a "conditional agreement" where the transfer of funds for services is anticipated*.

European partnerships

The following forms of collaborations are examples of this type of European partnerships:

- **EU Consortiums funded by the EC**

Partnership and collaboration projects between European health data platforms could be done through the establishment of European consortiums funded by the European Commission through e.g., H2020, Horizon Europe, EU4 Health program ...

- **European Research Infrastructure Consortium (ERIC)[3]**

The European Research Infrastructure Consortium (ERIC) is a specific legal form that facilitates the establishment and operation of Research Infrastructures with European interest. The ERIC allows the establishment and operation of new or existing Research Infrastructures on a non-economic basis
The European Commission provides practical guidelines to help potential applicants.
The ERIC becomes a legal entity from the date the Commission decision setting up the ERIC takes effect.

[2] https://acqnotes.com/acqnote/careerfields/memorandum-of-agreement-moa
[3] European Research Infrastructure Consortium (ERIC)

An ERIC can carry out some limited economic activities related to this task.

Procedures to obtain a formal commitment of a state to become a member or host an ERIC vary from country to country. The stakeholders of future ERICs are advised to work, well in advance, with their national authorities when preparing an ERIC.

ERIC partnership could have some advantages such as:
- a legal capacity recognised in all EU countries
- flexibility to adapt to specific requirements of each infrastructure
- a faster process than creating an international organisation
- exemptions from VAT and excise duty.

In order to establish an ERIC, partners should meet the following requirements:

- it must be a European joint-venture (can also allow the participation of countries from outside the EU)
- the infrastructure is necessary to carry out research programmes and projects
- it represents added value in the development of the European Research Area (ERA) and significant improvement in the relevant scientific and technological fields
- effective access is granted to the European research community in accordance with the rules established in the statutes
- it contributes to the mobility of knowledge and/or researchers within the ERA
- it contributes to the dissemination and optimisation of the results.

- **EU eHealth network[4]**

The purpose of the creation of the eHealth network is to support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

The eHealth Network was regulated in Article 14 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.
The eHealth network partners aim to:
- work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications
- draw up guidelines on a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and effective methods for enabling the use of medical information for public health and research
- support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

[4] Article 14:
Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (europa.eu)
Other information here:
eHealth Network (europa.eu)

STEP 5: Defining a partnership comitology

A comitology is a set of specific bodies and committees organising, in particular, the creation, modification or operation of committees dedicated to the conduct of projects.
The objective of the comitology organisation is to improve the project management, because it allows to keep a control on its implementation, to follow and to arbitrate the key points.
A well-organised comitology guarantees the consistency between the decisions to be taken and the goals of the project, particularly with regard to project deadlines. Its function is multiple. It serves the overall monitoring of the project's progress and is the forum for decision-making in accordance with the project's objectives.
It is very important to define a comitology for the management of the partnership before launch. This will allow to:

- Specify the distribution of the roles and responsibilities between the partners
- Build an effective project/partnership roadmap, enable coordination and progress monitoring.

STEP 6: Defining dissemination and communication activities

All communication and dissemination activities should be based on an integrated communication concept and strategy implemented by a joint effort of all partners.
Main dissemination and communication activities include scientific, press, event-based and social-media communication activities

These activities aim to:

- Promote the activities and results of the partnership are promoted
- Make the results of the project partnership visible and available to the target audience
- Support the deployment of the partnership
- Demonstrate the value of a cross-border partnership for the secondary use of health data and thus maximise the impact of the partnership.

4. Main obstacles encountered in establishing a cross-border partnership

As a matter of fact, many European countries possess substantial health data assets, which are however very fragmented and scattered across Europe with data sources of uneven quality and different governance models and access policies for reuse and sharing.

Cross-border secondary use of health data still faces many obstacles that could be summarised as follows:

- **Legal:** cross-border use faces complex regulatory procedures and pricing models of several countries at the same time, particularly for use cases involving the cross-referencing of data health, which highly impacts the development of digital health solutions.
  As identified in the Milestone 5.1 & 5.2 Summary of results: case studies on
  barriers to cross-border sharing of health data for secondary use, legal issues could also be due to:

  - Lack of a common European interpretation of what constitutes 'sufficient anonymisation' to transform personal data to non-personal data
  - Lack of a common European interpretation of what constitutes 'pseudonymisation'
  - Lack of a common European interpretation of what is and is not 'secondary use' of data.

- **Security:** high cybersecurity and ethics requirements due to the sensitivity of these data are also a harmonisation challenge.
- **Funding:** Several projects do not succeed due to insufficient funding. It is thus crucial not to overlook the Specification of the resources and or funding needed for the partnership phase and define a sustainable economic model before starting a project.
- **Data interoperability:** in the context of the fragmentation of the information systems used in healthcare institutions, lack of standards, interoperability and procedures makes the use of data complicated for large cross-disciplinary and cross-border research projects.
- **Data quality:** especially for data that were not originally collected for research purposes.
- **Trust and transparency:** including political, social and organisational factors and citizens engagement.

5. Conclusion

This document proposes generic guidelines on how to establish a cross-border partnership to be shared and discussed with European stakeholders.

In particular, it identifies 6 main steps to set up such a partnership, with a focus on the particularities of data sharing projects. In addition, it provides a summary of current obstacles on cross-border partnerships.

Alignment on the steps and obstacles of setting up cross-border partnerships should facilitate new partnerships and draw attention to the barriers encountered in order to resolve them.

As the European Union seeks to establish a European Health Data Space and to encourage the secondary use of health data, such cross-border partnerships will likely become more frequent and play an important role for research and innovation.

Annexes: Illustrations of peer-to-peer and cross-border partnership types for the secondary use of health data.

Annex 1: Memorandum of Understanding (MoU) between Findata and The Health Data Hub

Findata and the HDH sought to define the appropriate framework to implement their collaboration, along with the goal of providing material and designing a transferable framework for other participating countries. They chose Memorandum of Understanding because it is a symbolic declaration on the partners' intention of working together, not as an obligation nor as a financial commitment. It is an umbrella allowing the two organisations to collaborate officially, within a commonly defined framework. The Memorandum of understanding does not facilitate any kind of data exchange between the two authorities.

1. Preparation work

The agreement between Findata and the Health Data Hub is resulting from more than 1-year of regular exchanges between two innovative entities, initiated in April 2020. Both organisations were driven by the same purpose: making health data more accessible for health research and innovation. Memorandum of understanding was prepared in several preliminary stages. Meetings were scheduled to address specific topics and to prepare the partnership. The topics of the meetings included discussing a shared vision for the collaboration and naming possible thematic areas to work together.

2. Shared vision for collaboration

Both parties expected the elaboration of an agile, practice-oriented approach and focus on themes that bring the most value for both organisations. The mutual vision for collaboration became facilitating the effective and safe secondary use of health data by respecting citizens' rights and freedoms and following FAIR (Findable, Accessible, Interoperable and Reusable) principles.

3. Activation plan and thematic areas of collaboration

In order to address the shared challenges as national health data platforms, Findata and the Health Data Hub constructed a memorandum of understanding around four main concrete axes of collaboration.

The first one focuses on the development of metadata catalogues. The second tackles existing challenges and recognizes best practises in data access and management. It entails the exploration of a potential future collaboration around synthetic data. The third axis of collaboration will revolve around international collaboration and fourth in international communication for example to promote activities conducted by Findata and the HDH.

4. Metadata catalogues

The objective is to share best practices and lessons learned in building comprehensive national metadata catalogues, i.e., in language translation of catalogues and variable descriptors.

The collaboration started with an initial meeting discussing challenges faced in developing metadata catalogues and sharing best practices.

Later, if relevant, collaboration could include activities such as cross-linking of each party's catalogues, communicative actions to help researchers to navigate the two catalogues; co-organizing an event of metadata descriptions as well as writing a common blog post or article to compare the processes of facilitating meta descriptions and highlighting the differences in two approaches.

5. Data Access and Management

Thematic area of data access and management was based on the need to learn more about different ways to facilitate safe but effective secondary use of data and to understand different practices between the two national actors. This axis included several independent themes, such as technological platform and tools, requirements for data environment (security, privacy and high-standard storage), possibilities of supporting researchers to match health datasets in two countries, discussing the different criteria for pseudonymization and anonymization, and practises of creating synthetic data.

Activities would first include several introduction meetings, possible co-written articles and co-organizing events on specific topics.

6. International collaboration and joint responses to calls/funding

The goal is to collaborate in international calls that focus specifically on data quality, infrastructure, development, testing, and/or capacity building and training and bilateral staff exchange.

7. International communication activities

International communication activities can include organisation of joint events and specific bilateral workshops within the thematic areas. Additionally, later it could mean joint publications (comparative analysis between the two platforms) and mutual social media support

Annex 2: **Research Use case**

A health data sharing partnership project can also take the form of a research project that will therefore involve the stakeholders' own country data as well as their own resources.

For this, a research protocol must be established before the start of the project in order to jointly define the conditions of the project and the sharing of responsibilities.

The following list is an example of elements that may be included in a research protocol for the sharing and secondary use of health data:

Use case
Use case title

History of modifications		

1. Summary of the use case

Briefly summarise the use case (context, problem, objectives)

2. Research Teams for the use case

Partner	**Country**	**Role**	**Team**
Name of the		Describe the	Name, title and function of team members and

institution		expertise and skill of the partner	role in the project

3. Nodes involved

Node		Country	Contact persons
Name of the institution			

4. Use case description

a. Context and challenges

Targeted pathology, objectives of the study, innovative character...

b. Expected benefits and impact on public health

Aims of the project: *to be explained in a clear manner* Benefits for public health: *Qualitative and quantitative* Benefits for EHDS: *Qualitative and quantitative* *The benefit of the project: it must bring a direct or indirect benefit for individuals, for society, or for the scientific community and specifically to public health. Describe these benefits in a clear and precise manner.*

C. Description of the data required for the use case

*→To be **duplicated** as many times as there are datasets by nodes/country*

Data Source 1 - Name	
Data Source	*Specify the data source and the producing entity for each country/node participating in the use case*
Description of the required data	*Describe:* ● *The typology and content of the desired data* ● *Target population* ● *Data period (Historical depth)* ● *Estimated volume of data*
Data availability	*Specify:* ● *Whether the database is existing or to be built; if existing, specify the origin of the data* ● *The completeness of the database with respect to the needs* ● *Whether the data are in the right format, annotated* ● *Whether they are available for the entire target population*
Linkages	*If you plan to link databases, specify the strategy of the linkage including data sources and linkage variables*
Data access procedure	*Provide a short overview of the data authorization and access procedure and timeliness*

5. Methodological summary

Please be as succinct as possible.

a. Study design

Describe the design of the study to be implemented (cohort, case-control, etc.) and indicate whether comparisons will be made. Specify whether the analyses are cross-sectional or longitudinal, and whether the study is prospective or historical.

Describe the endpoints that will be studied. The advantages of the design chosen to meet the objectives of your project can be mentioned in this chapter.

b. Description of the study population

Describe the study population by specifying:

- *Inclusion and exclusion criteria in terms of population characteristics, target pathologies and geographic scope (regional, national, multicentre etc.).*

Provide an estimate of the size of the population you wish to study, indicate the underlying calculations, if any.

c. Variables

Define the list of the study variables by type of variable.

Example:

Topic	***Variables***
Socio-economic information	*civil status, employment status, income decile, residency in collectivities, etc.*
Hospitalisation	*Data on hospitalised patients with a confirmed COVID-19 diagnostic*

d. Methods, data processing and analysis

Indicate the tool(s) (development framework, software, etc.) that will be used to analyse the data in the study; describe these tools with respect to the research question posed and the data available.
Detail the mathematical or algorithmic methods (statistics, inference, modelling, machine learning, etc.) that will be used.

6. Maturity and technical feasibility of the use case

a. Target vision

Present in a synthetic way the technical solution and the algorithmic approach associated with the use case.

b. Key milestones

Present in a synthetic way the main milestones of the use case schedule.

c. Stage of progress of the use case

Specify if a similar study has already been conducted on a smaller population for example, if the identified team has experience on the subject...

d. Anticipated risks

Describe the main risks and anticipated obstacles related to the realisation of the project as well as the mitigation measures put in place to reduce these risks (risk of data access, legal issues, technical issues, resources…)

7. Results

- *Is the use case likely to produce initial results in a relatively short time frame?*
- *Do all the data have to be available for the use case to produce initial scientific results?*

Specify precisely the key potential results of the use case.

8. Total budget identified for the use case

Detail the budget required to achieve the benefits presented in.

→To be duplicated as many times as there are nodes/country

Node 1: XXXXXX

Action	Work details	Deadline	Required resources (Person month)

Upload of data from local hubs on the node platform (if needed)			*Specify the skills to be gathered and the associated estimated workload in person months*
Data preparation strictly necessary for operating the use case			
Run of the use case by the Research Team			
Costs of accessing health data on the node platform			