HEALTH DATA HUB

Toolkit for users

Simplified procedure for accessing aggregated SNIIRAM data and/or the ESND

Toolkit

References:
CNIL and Legifrance

The simplified access procedure* to aggregated data from the National Health Insurance Inter-Scheme Information System (SNIIRAM) and/or the Sample of National Health Data System (ESND) is a procedure that allows you to access these data within **a maximum of 15 days** without having to obtain authorisation from CNIL. Only approval from the HDH is required and granted once your project meets 8 conditions.

The purpose of this document is to help you **determine whether your project meets these conditions** and to **outline the submission process** of your request to the HDH.

HEALTH DATA HUB

*For more information on simplified procedures, please consult our toolkit for data access procedures.

Data sources covered by the access procedure

The data access procedure presented in this toolkit covers **two data sources**:

The sample of the SNDS* (ESND)

Created by the CNAM, the ESND is a **random sample of 2/100 of the people** whose data appear in the SNIIRAM. It contains the following information:

- the inter-scheme consumption datamart (DCIR)
- data contained in the “Program for the medicalization of information systems” (PMSI) in the fields of medicine, surgery, obstetrics (MCO), follow-up and rehabilitation care (SMR), collection of medical information for psychiatry (RIM-P) and hospitalisation at home (HAD).

SNIIRAM aggregated data (datamarts)

These are thematic databases of aggregated data called 'datamarts geared towards monitoring expenditure' (DAMIR) or 'analysis of healthcare provision' (AMOS), as well as management charts for biology and pharmacy.

Acronyms

*For more information on the National Health Data System (SNDS - Système National des Données de Santé), please visit our website (only available in French at that time).

Commitments of the project leader

The project leader is the data controller* and must make the following commitments:

- Determine whether the procedure is applicable to the project;
- Comply with the framework laid down by the simplified procedure throughout the data treatment's lifecycle;
- Document the compliance of its data processing;
- Register the processing in the register of processing activities;
- Comply with the regulatory obligations related to the use of data from the National Health Data System (SNDS), as decribed below.

HEALTH DATA HUB

*He / She is the person, public authority, department or body that determines the aims, objectives and means of the study. The data controller assumes *legal responsibility for the data processing.*

Commitments of the project leader for the use of SNDS data

The data available under this simplified procedure come from the SNDS

When making a request, the data controller commits to **complying with all the legislative and regulatory provisions related to the SNDS** and, in particular, the following requirements:

Requirement 1

To carry out a data processing justified by its public interest and to avoid using the data for prohibited purposes*.

Requirement 2

To comply with the security guidelines applicable to the SNDS, settled in the Order of May 6th 2024

Requirement 3

To comply with transparency obligations for projects using SNDS data. This includes transmitting the study results and the associated methodology to the HDH once the analyses are complete.

* These purposes are:
- the promotion of healthcare products to healthcare professionals or healthcare product establishments;
- the exclusion of cover from insurance contracts
- the modification of insurance contributions or premiums for an individual or group of individuals.

Conditions for obtaining the approval

In addition to complying with the provisions related to the use of SNDS data, the request must meet **8 cumulative conditions** to obtain approval:

Condition 1

The project must pursue one of the 6 purposes specific to the procedure

Condition 2

The scientific relevance of the project must be justified by 3 external experts from at least two different specialities

Condition 3

The project must not cross-reference several potential identifiers*. A justification for the use of a potential identifier must be provided.

Condition 4

A justification must be provided for the historical depth requested among the two choices available**.

Condition 5

The data processing is carried out on the secure portal of CNAM

Condition 6

The access to the portal must be limited to the time required and cannot exceed 24 months, renewable once with a reasonable request.

Condition 7

The data controller takes appropriate steps to make information about the study publicly available.

Condition 8

If the data controller is an insurer or from a health industrial company, the processing must be carried out by a research laboratory or a CRO*** that has made a commitment to comply with the guidelines settled by the Order of 17 July 2017

HEALTH DATA HUB

*These potential identifiers are: year and month of birth, municipality of residence, dates of care, date of death and municipality of death.
** The historical depths available are 9 years in addition to the current year and 19 years in addition to the current year.
*** Clinical Research Organization

Focus on the project's purposes

The purpose of the project must **be clear and explicit in the submitted protocol**.

It must meet one of the **following 6 objectives**:

- Comparative assessment of healthcare provision;
- Evolution of health care practices;
- Comparative analyses of healthcare activities;
- Description and analysis of pathologies and care pathways;
- Epidemiological and/or medico-economic studies, including studies for preparing discussion files and meetings with the relevant authorities and committees, or studies for surveillance purposes;
- Feasibility studies in the context of research involving or not human subjects (research on individuals vs research on data).

Focus on scientific relevance

Scientific relevance must be **assessed by 3 experts external to the data controller, from at least two different specialities**, using a standard grid (only available in French at that time).

7 criteria are assessed:

Criteria 1

Clarity and relevance of the intended purpose

Criteria 2

Clarity and consistency of objectives with the intended purpose

Criteria 3

Suitability of the method for the objectives pursued

Criteria 4

Suitability of the data requested (aggregated data or ESND) for the intended purpose

Criteria 5

Requirement to use one of the potential identifiers

Criteria 6

Relevance of the requested historical depth

Criteria 7

Possible limitations of the project

Focus on informing people

Registering the study in the HDH's public directory is not sufficient to meet the transparency obligations required by the procedure.

To compensate for the fact that individual information is not possible with aggregated data from SNIIRAM and ESND, the data controller must take **appropriate measures to make the study information publicly available**.

Thus, the data controller must at minimum **publish collective information* on its website** and, where applicable, **on the website of the research laboratory or CRO he is working with.**

Other channels for disseminating information can also be used, such as:

- Communication on social media, regional media and with patient associations;
- Publication of a press release;
- Sending of newsletters;
- Display in premises, waiting rooms, etc.

Please note that when a data controller carries out several studies as part of this procedure, he or she must set up a transparency portal containing general information on the SNDS, as well as an information note specific to each study.

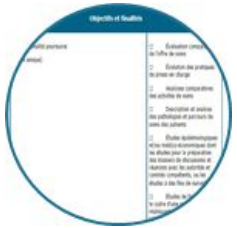
*The information provided must comply with Article 14 of the RGPD (only available in French at that time).

The HDH application process

The submission file consists of **5 documents following standard templates**

Protocol

Summary



Declarations of interest by the data controller and subcontractor, if applicable

3 expert assessments

Checklist for project leaders

Key milestones

Submission of the application on the HDH* website

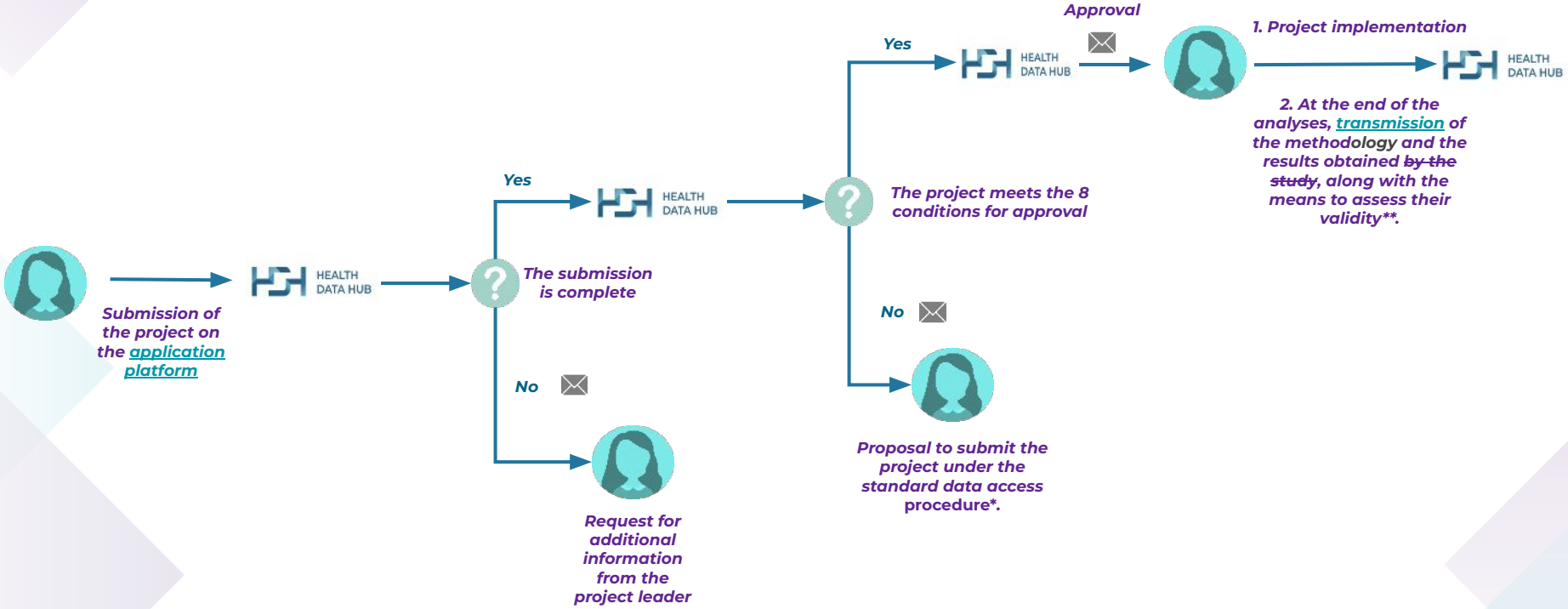
Evaluation and response from the HDH

<= 15 days

Once the analyses are completed, transmission of the results of the study by the data controller in order to feed the public directory of projects

*The characteristics of the project collected from the application form will be published in the public directory in order to comply with the transparency obligations.

Summary



Caption: Project leader Mail service of the submission platform

HEALTH DATA HUB

*For more information on the standard procedure, please consult our toolkit for access procedures.
** More information in the toolkit on transparency obligations concerning projects that use SNDS data.

Open resources: HDH support

Helping project leaders complete their data access applications

1

[Toolkit](#) for health data access procedures

[Toolkit](#) for transparency obligations

Increase knowledge on the main SNDS database and other data sources

2

[Citizen training on the SNDS](#)

[Training on SNDS data and access procedures](#)

[MOOC](#) / e-learning on the SNDS

[Collaborative documentation](#)

[Public directory of projects](#)

[Support forum](#)

Acronyms

AMOS: Assurance Maladie Offre de Soins *(Analysis of healthcare provision)*

CESREES: Comité Éthique et Scientifique pour les Recherches, les Études et les Évaluations dans le domaine de la Santé *(Ethical and Scientific Committee for Research, Studies and Evaluations in the Health Sector)*

CNAM: Caisse Nationale d'Assurance Maladie *(National Health Insurance Fund)*

CNIL: Commission Nationale de l'Informatique et des Libertés *(French Data Protection Authority)*

CRO: *Clinical Research Organization*

DAMIR: Dépenses d'Assurance Maladie Inter-Régimes *(Inter-Scheme Health Insurance Expenditures)*

DCIR: Datamart de Consommation Inter-Régime *(Inter-Scheme Consumption Datamart)*

ESND: Échantillon du Système National des Données de Santé *(Sample of the National Health Data System)*

HAD: Hospitalisation A Domicile *(Hospitalization at home)*

HDH: *Health Data Hub*

Acronyms

MCO: Médecine, chirurgie, obstétrique *(Medicine, surgery, obstetrics)*

PMSI: Programme de Médicalisation des Systèmes d'Information *(Medicalisation of Information Systems Program)*

RIM-P: Recueil d'Information Médicalisé pour la Psychiatrie *(Collection of Medical Information for Psychiatry)*

RMO: Responsable de la Mise en Oeuvre *(Responsible for implementation)*

RT: Responsable de Traitement *(Data controller)*

SNDS: Système National des Données de Santé *(National Health Data System)*

SNIIRAM: Système National d'Information Inter-Régimes de l'Assurance Maladie *(National Health Insurance Inter-Regime Information System)*

SMR: Soins Médicaux et de Réadaptation *(Medical and rehabilitation care)*

To find out more

If, after consulting this toolkit, you still have questions about the eligibility of your project for the simplified procedure, you can:

- Consult the CNIL decision adopting this procedure;
- Ask your questions on the forum;
- Get in touch with us. Please give us as much detail as possible about your project and any questions you may have, so that we can give you the best possible answer.