



HEALTH  
DATA HUB

# Toolkit for users

Health data access procedures  
in France

# Accessing health data in France

In France, access to health data is submitted to regulations. Procedures, rules and timeframes to access the data may vary based on which conditions you meet and whether the requested data has already been collected or not.



The purpose of this toolkit is to help you **characterise the type of research you are considering** and then help you **identify and implement the applicable procedure**.

You are not in the scope of this toolkit, if you use :

- ❖ data that are **perfectly anonymised** : data protection principles do not apply in this case.
- ❖ personal data that are not health data

*For more information about anonymisation, please visit the [CNIL website](#).*

*To learn more about the definition of health data, please visit the [CNIL website](#).*

# Accessing health data in France

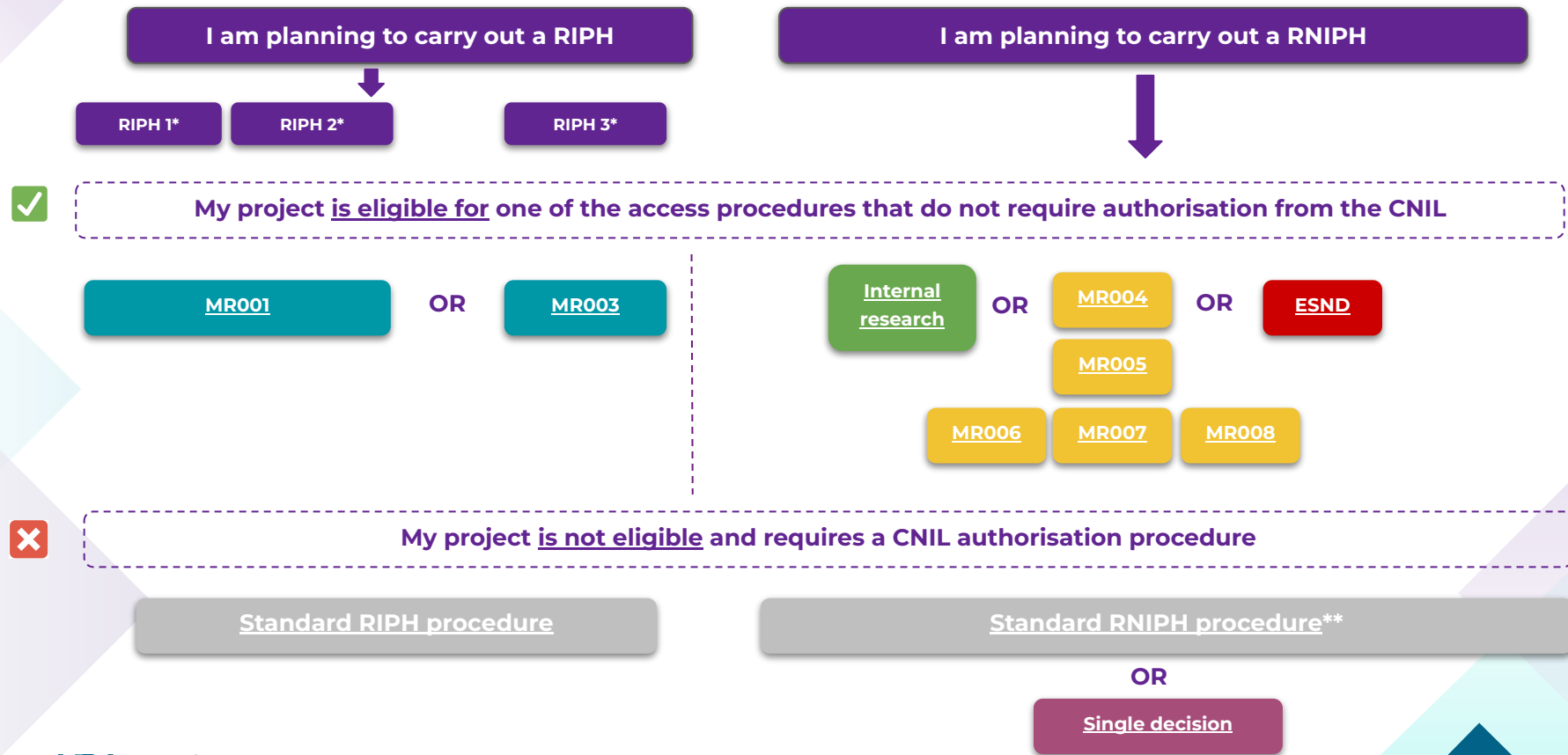
Two main types of research requiring the use of health data exist in France and involve different procedures for their implementation: research involving human subjects and research not involving human subjects. Traditionally, whenever you wish to re-use personal data, you need to obtain authorisation from the national data protection agency, CNIL, except in very specific cases, referring to simplified procedures.

In order to identify the right regulatory process for your project, the two following questions need to be raised:

- ❖ **Question n°1:** Does my research project involve human subjects (research on individuals vs research on data) ?
- ❖ **Question n°2:** Is my research project eligible for a data access procedure exempted from a CNIL authorization ?

This toolkit provides you with assessment criteria to help you answer these questions.

# Overview of existing procedures for conducting health research



# Question n°1

I characterize my research project :

**Question n°1: Does my research project involve human subjects  
(research on individuals vs research on data) ?**

# Research project Involving Human Subjects (RIPH)

To qualify as a RIPH, the research project must meet two cumulative conditions. It must :

1

**Be carried out using the human body** : meaning that additional data collection is necessary for the research, i.e. beyond the data already collected as part of the healthcare procedures relating to the person. In other words, if the research was not carried out, the data would not be collected.

2

**Lead to the development of biological or medical knowledge :**

- ❖ **Biological** knowledge refers to the functioning of the human organism in a broad sense (development, physiology, behaviour, reactions to the environment)
- ❖ **Medical** knowledge refers to prevention, diagnosis or treatment of diseases or disabilities.

# Research project Involving Human Subjects (RIPH)

There are **three categories of RIPH**, depending on whether or not the research involves a procedure/ intervention and on the risks incurred by the person who undergoes it:

## Category 1

The research project entails a procedure that is not justified by the person's usual care and is not without risks for them.

*A clinical trial involving a drug or an innovative surgical procedure.*

## Category 2\*

The research project entails a procedure with minimal risks and constraints for the person.

*Low-risk blood sampling, medical imaging without radiation or contrast injection*

## Category 3\*\*

The research does not entail a procedure but observation of the person and does not carry any risks.

*Audio or video recordings, excluding medical imaging, or non-invasive anthropometric measurement.*



**Determining the category of RIPH is important in order to identify the appropriate procedure to follow.**

## Research project Not Involving Human Subjects (RNIPH)

**A research project not involving human subjects (RNIPH)** is defined as opposed to RIPH: If one or none of the conditions to qualify the research as a RIPH are met, then the research is a RNIPH

In other words, a RNIPH is a research that

- ❖ is based on data already collected in the context of care or during a previous research (retrospective data)
- ❖ and/or is based on data collected as part of patient care, continuously, or specifically collected for research purposes without contributing to the development of biological or medical knowledge (prospective data)



*An example of RNIPH : a research thesis on data from medical records or research requiring access to SNIIRAM (French healthcare claims database) data only.*



## Examples of RIPH/RNIPH

# RIPH

### Purpose

Setting up a **cohort** of people who have contracted a severe form of coronavirus

### Objective

Extend existing monitoring beyond the time when these people are treated in hospital, and offer them long-term monitoring of their health and quality of life to provide **information on the risk of after-effects**.

### Data source

**Self-questionnaires** available on a website **to be completed** twice a year for ten years.

Leading to the development of biological and medical knowledge



Research involving the human body



## Examples of RIPH/RNIPH

# RNIPH

### Purpose

Carrying out a satisfaction survey of patients hospitalized for a severe form of coronavirus.

### Objective

To find out how **satisfied patients are with the care they receive** in our facilities, so that we can take the necessary steps to improve our services.

### Data source

**Self-questionnaires** available on a website to be completed twice a year for ten years.

Leading to the development of biological or medical knowledge



Research involving the human body



## Examples of RIPH/RNIPH

# RNIPH

*Purpose*

Leading to the development of biological and medical knowledge



Research into the care of people with multiple sclerosis.

*Objective*

Analysing the **impact of the coronavirus on the care of** people with multiple sclerosis.

*Data source*

**Medical records** of health establishments taking part in the research

Research involving the human body



## Question n°2

**Is my research project eligible for a data access procedure which does not require an authorization from the CNIL ?**

*Prerequisite: I know whether my research project involves human subjects or not.*

## Various modalities of data access

**1** There are three ways of accessing health data for research purposes in France:

- ❖ **Internal research** not involving any formality with the CNIL ;
- ❖ **Simplified procedures** that do not require authorization from the CNIL: these can be used as soon as the planned research meets a certain number of conditions set out in the legislation ;
- ❖ The **standard procedure**, if none of the two previous methods is applicable: the CNIL's authorization must then be obtained after receiving the opinion of the competent expert committee\*.

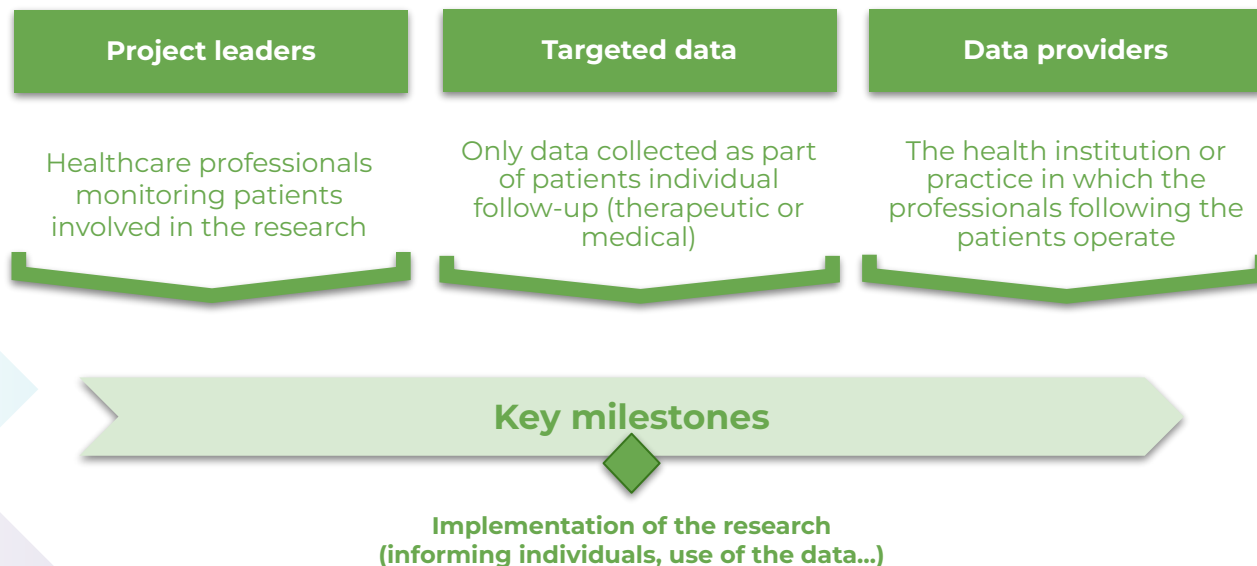
**2** In all cases, the project leader relating to the definition of data controller\*\*:

- ❖ Determines the applicable procedure to the research project ;
- ❖ Must respect the framework set by the internal research, the simplified procedure or the authorization throughout the duration of data processing ;
- ❖ Lists each processing operation into the record of processing activities.

\* This may be the CPP - Committee for the Protection of Persons - ethics committee for RIPH or the Ethics and Scientific Committee for Research, Studies, and Evaluations in the Health Sector (CESREES) for RNIPH.

\*\* It is the person, public authority, service or organisation that determines the purposes, objectives and means of the study and assumes legal responsibility for the processing.

# Internal research



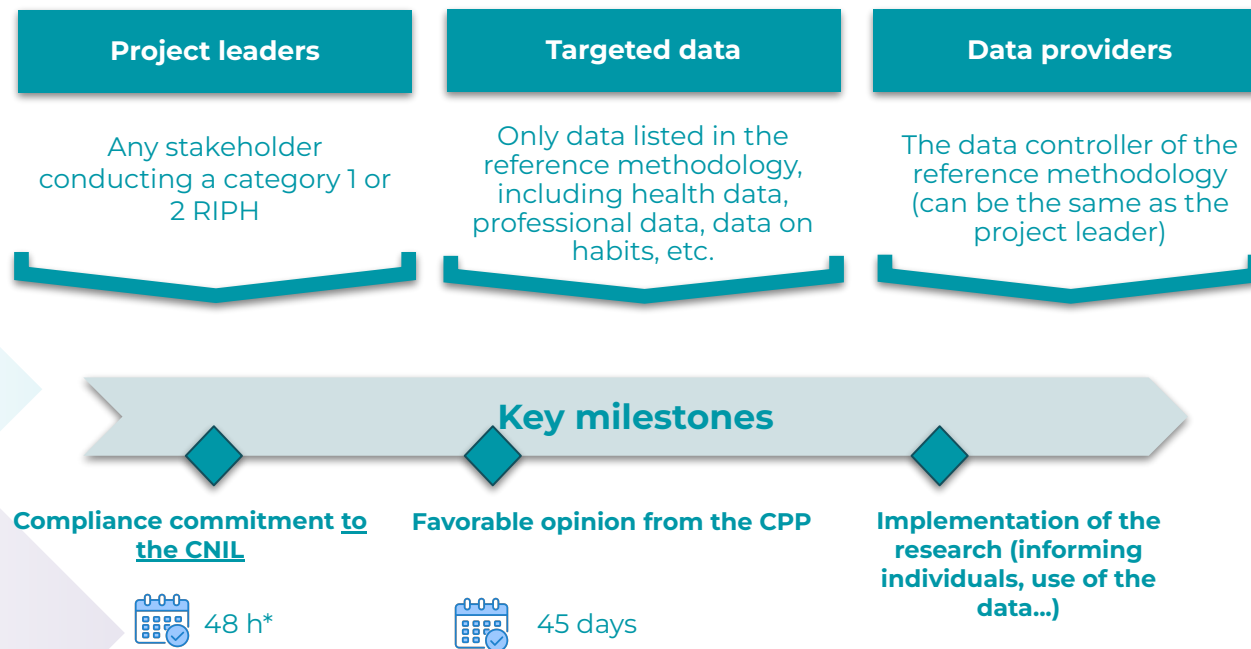
## Critical points

The research must be conducted for the exclusive use of professionals involved in the follow-up of the patients concerned



*Example: study carried out by a midwife on pregnant women she has followed in her practice over the last five years to obtain indicators to improve their care.*

# RIPH reference methodology : MR-001



## Critical points

- (1) The express consent of individuals must be obtained
- (2) Data from the SNDS (French National Health Data System) cannot be used (except in the case of a child system)
- (3) The collection of NIR (social security number) is not allowed



Example: Covid-19 vaccine immunogenicity study

# RIPH reference methodology : MR-003



## Critical points

- (1) The individuals concerned must not have opted-out of participation in the research.
- (2) Data from the SNDS cannot be used (except in the case of a daughter system)
- (3) The collection of NIR (social security number) is not allowed

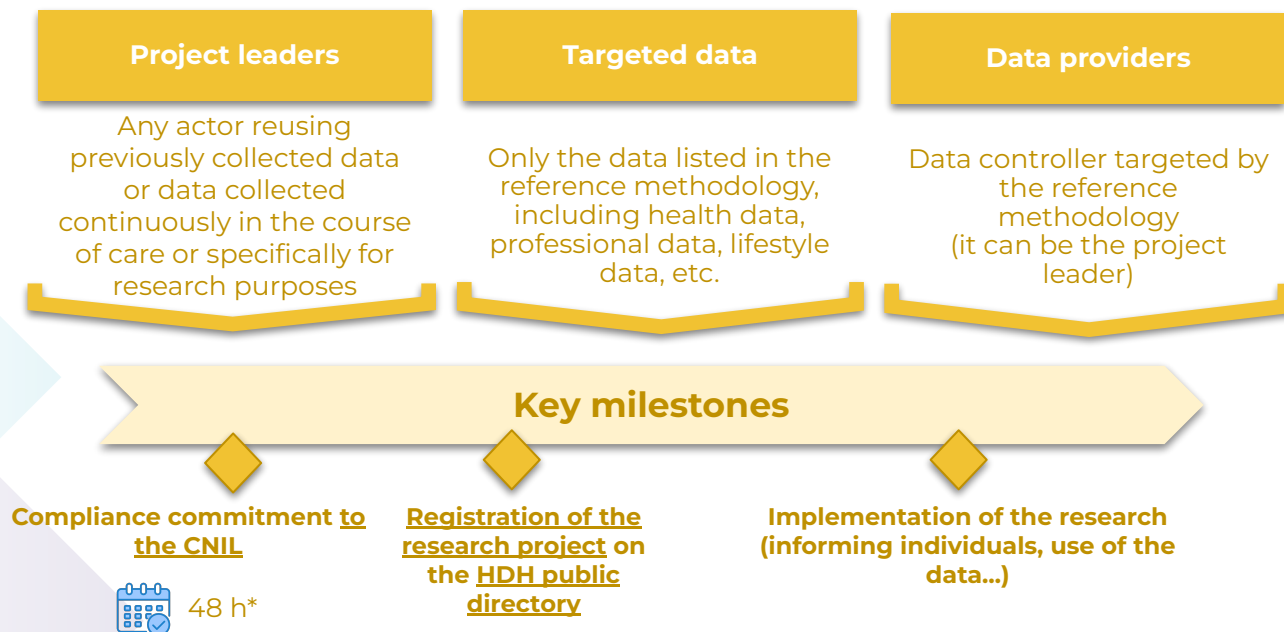


*Example: study requiring the collection of an additional dose of blood to test for HIV, not included in the initial patient care*



# RNIPH reference methodology : MR-004

References :  
Légifrance et CNIL



1491  
projects in  
2024

## Critical points

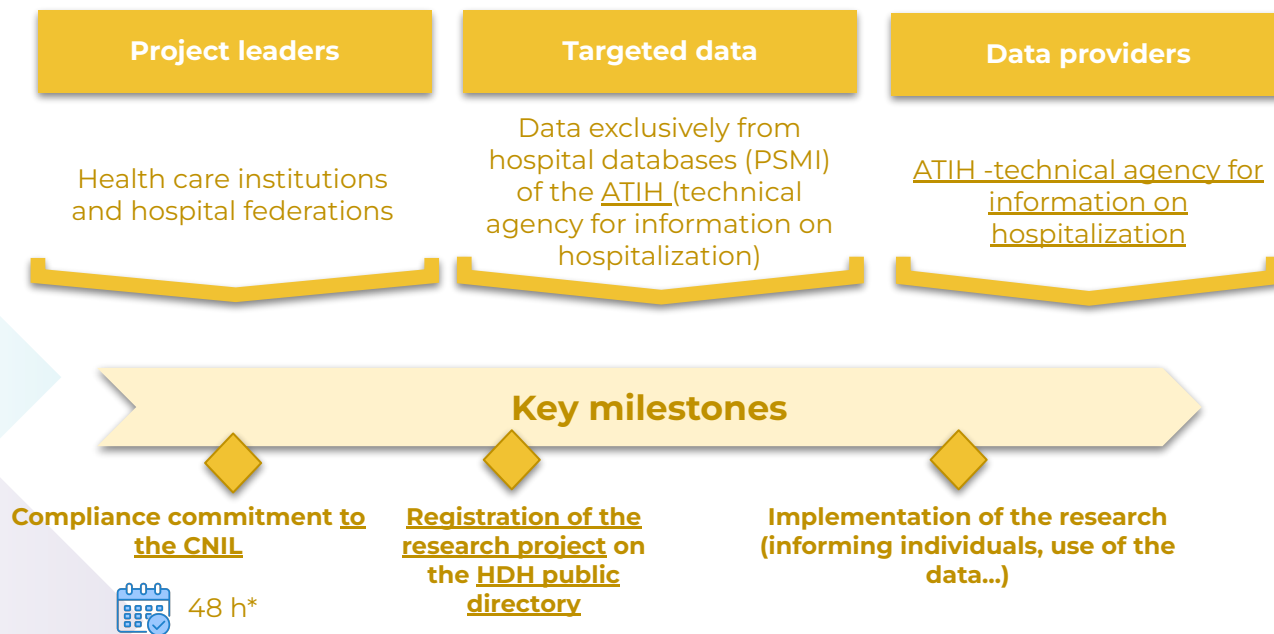
- (1) Data subjects must be **individually informed**
- (2) No data directly identifying the patient should be used (except for health professionals who have followed the patient)
- (3) Data from the SNDS may not be used (except in the case of a child system)



*Example: study on the care of premature babies based on medical records from the university hospitals in the Occitanie region*

# RNIPH reference methodology : MR-005

References :  
National Gazette  
Légifrance et CNIL



17  
projects in  
2024

## Critical points

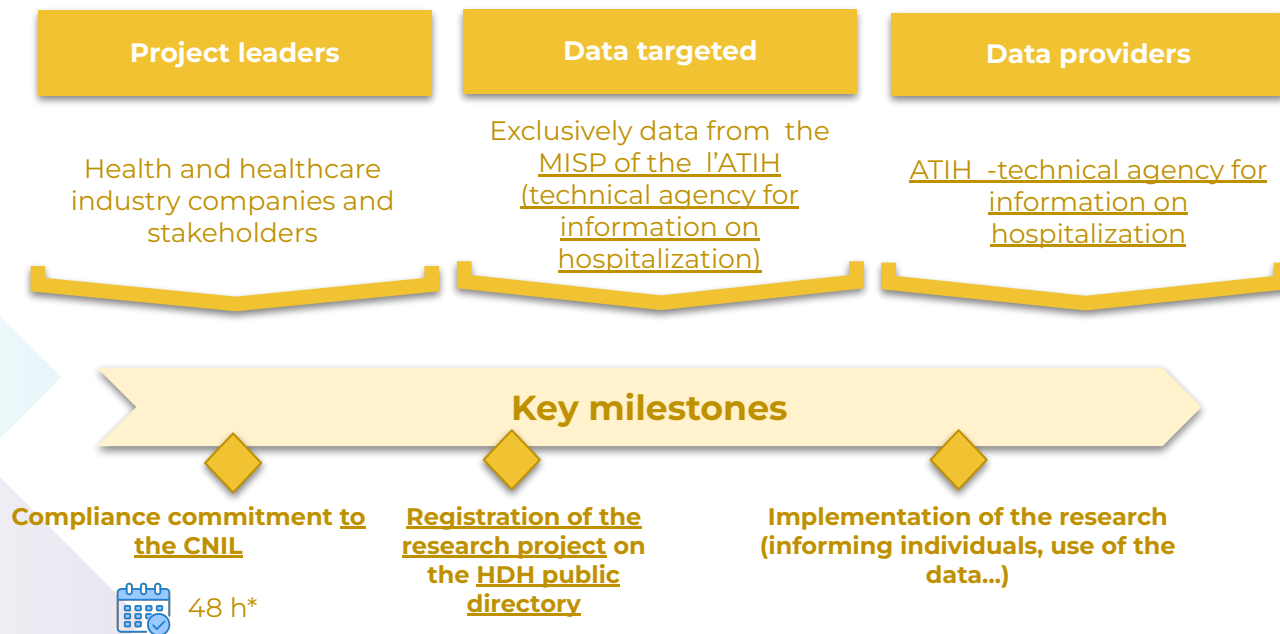
Data can only be processed on the **ATIH platform**



Example: study of the re-hospitalization rate following a stroke

# RNIPH reference methodology : MR-006

References :  
National Gazette  
Légifrance et CNIL



65  
projects in  
2024

## Critical points

- (1) The study must be carried out by a research laboratory or study office that has made a compliance commitment to the CNIL
- (2) An audit of the study's objectives and the use of the results by the project leader must be conducted



Example: study of multiple sclerosis cost of care.

# RNIPH reference methodology : MR-007

## Project leaders

Any actor justifying that the processing of data from the main SNDS database for the purposes of research, study or evaluation is necessary for the pursuit of a **mission of public interest**.

## Target data

Only data from the **SNDS main database**

## Data providers

The data in the main SNDS database must originate **exclusively and directly from the CNAM**

## Critical points

- (1) The **maximum historical** depth is 9 years in addition to the current year.
- (2) **Collective information** must be provided
- (3) Processing must be carried out in a **controlled environment** as defined in the reference methodology.

## Key milestones

Compliance commitment to the CNIL



48 h\*

Submission of the application to the CESREES and receipt of an expressly favourable opinion with or without a recommendation

Modification of the application by the data controller to take into account the CESREES recommendations, if applicable

Registration of the project in the HDH public directory and dissemination of information to the public

Research implementation (access to data, data processing, etc.)

Transmission of the study results and the associated methodology to the HDH

Report to the CNIL and/or the CESREES every three years



*Example: Analysis of lupus care in towns and hospitals since 2016*

\* This is the time taken to receive the acknowledgement of receipt once the commitment has been made on the site.

# RNIPH reference methodology : MR-008

## Project leaders

Any actor justifying that the processing of data from the SNDS main database for the purposes of research, study or evaluation is necessary for the pursuit of a **legitimate interest**.

## Target data

Only data from **the SNDS main database**

## Data providers

The data in the main SNDS database must come **exclusively and directly from the CNAM**

## Critical points

- (1) The study must be **carried out by a research laboratory or study office** that has made a compliance commitment to the CNIL.
- (2) The **maximum historical** depth is 9 years in addition to the current year.
- (3) **Collective information** must be provided
- (4) Processing must be carried out in a **controlled environment** as defined in the reference methodology.

## Key milestones

**Compliance commitment to the CNIL**



48 h\*

**Submission of the application to the CESREES and receipt of an expressly favourable opinion with or without a recommendation**

**Modification of the application by the data controller to take into account the CESREES recommendations, if applicable**

**Registration of the project in the HDH public directory and dissemination of information to the public**

**Research implementation (access to data, data processing, etc.)**

**Transmission of the results of the study and the associated methodology to the HDH**

**Report to the CNIL and/or the CESREES every three years**



*Example: post-registration study of the outcome of patients implanted with the device known as "TEST".*

\* This is the time taken to receive the acknowledgement of receipt once the commitment has been made on the site.

# Summary of simplified procedures applying to RNIPHS

## MR-004

ny stakeholder reusing previously collected data or data collected continuously in the course of care or specifically for research purposes



Only the data listed in the reference methodology, including health data, professional data, lifestyle data, etc.



**Individual information** must be provided

No data from the SNDS main database is used **unless it comes from a subsidiary system**



## MR-005

Healthcare establishments and hospital federations



Only **data from the PMSI of the ATIH**



Data can only be processed on the ATIH platform



Target data



Critical points

## MR-006

Health and Healthcare industry companies and stakeholders

Only **data from the PMSI of the ATIH**

The study must be **carried out by a research laboratory or study office**

An audit must be carried out by the project leader



Project leaders

# Summary of simplified procedures applying to RNIPHs

MR-007\*

Any stakeholder implementing a project necessary for the pursuit of a **mission of public interest**



**The SNDS main database**  
(9 years in addition to the current year)



Providing collective information

Processing data in a controlled environment

**The data must originate exclusively from the CNAM**



Project leaders



Target data

MR-008\*

Any stakeholder implementing a project necessary for the pursuit of a **legitimate interest**

**The SNDS main database**  
(9 years in addition to the current year)

Providing collective information

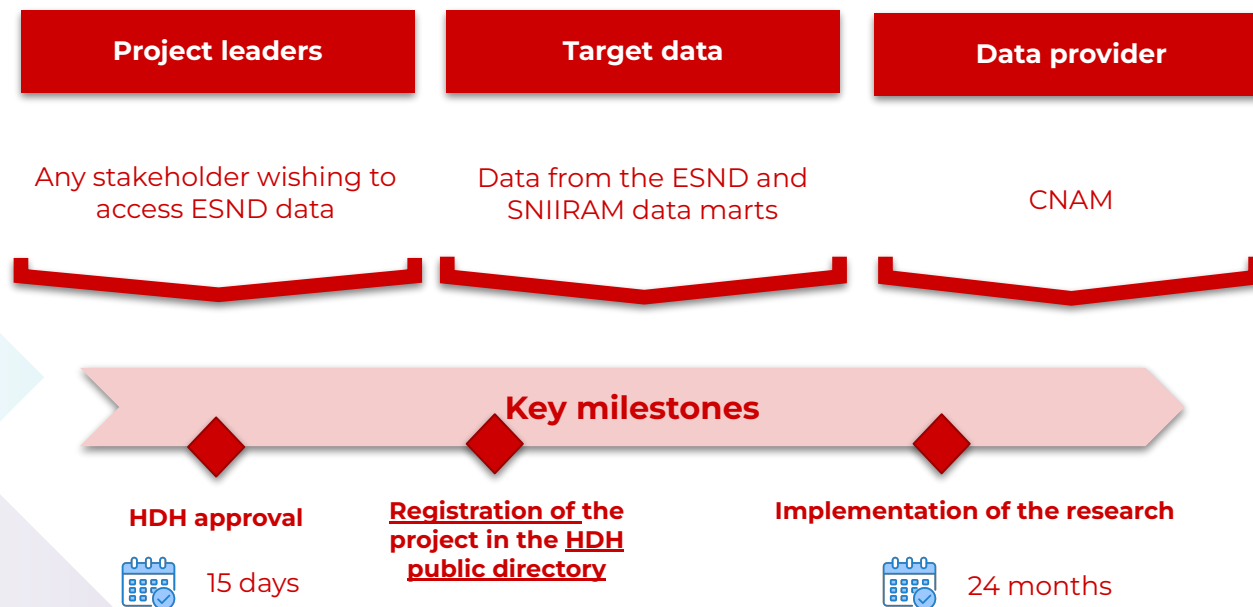
Processing data in a controlled environment

**The data must originate exclusively from the CNAM**



Critical points

# Simplified access to the SNDS "ESND" sample



## Points of attention

- (1) Use of a **single potential identifier**
- (2) The period of access may not exceed **two years**.
- (3) Access to data is via the **CNAM platform**.
- (4) The project must be assessed by **three experts external to the project leader**
- (5) Appropriate measures must be taken to make **the information** relating to the study **publicly available**.

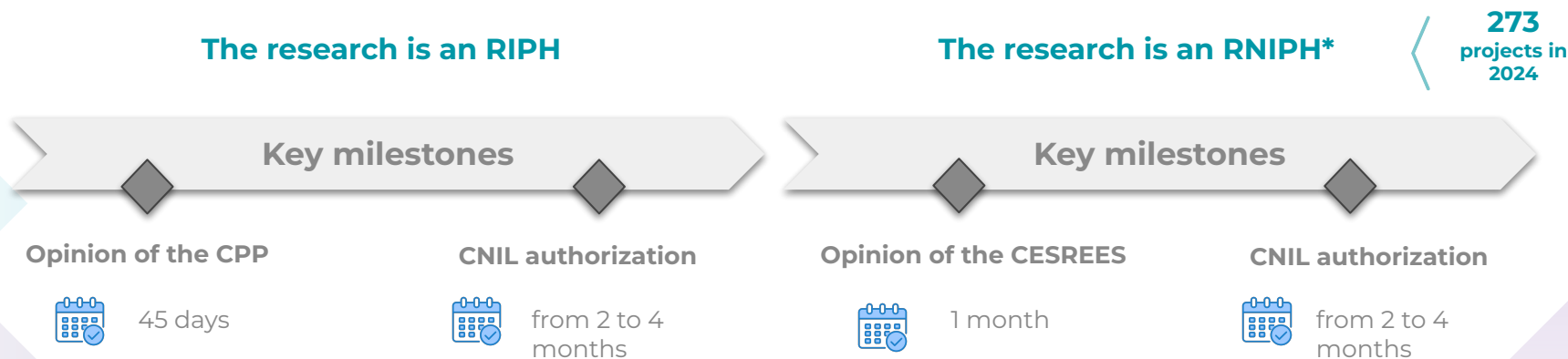


*Example: Study on healthcare consumption by patients suffering from asthma in France*



# The standard procedure implies prior authorization to access the data

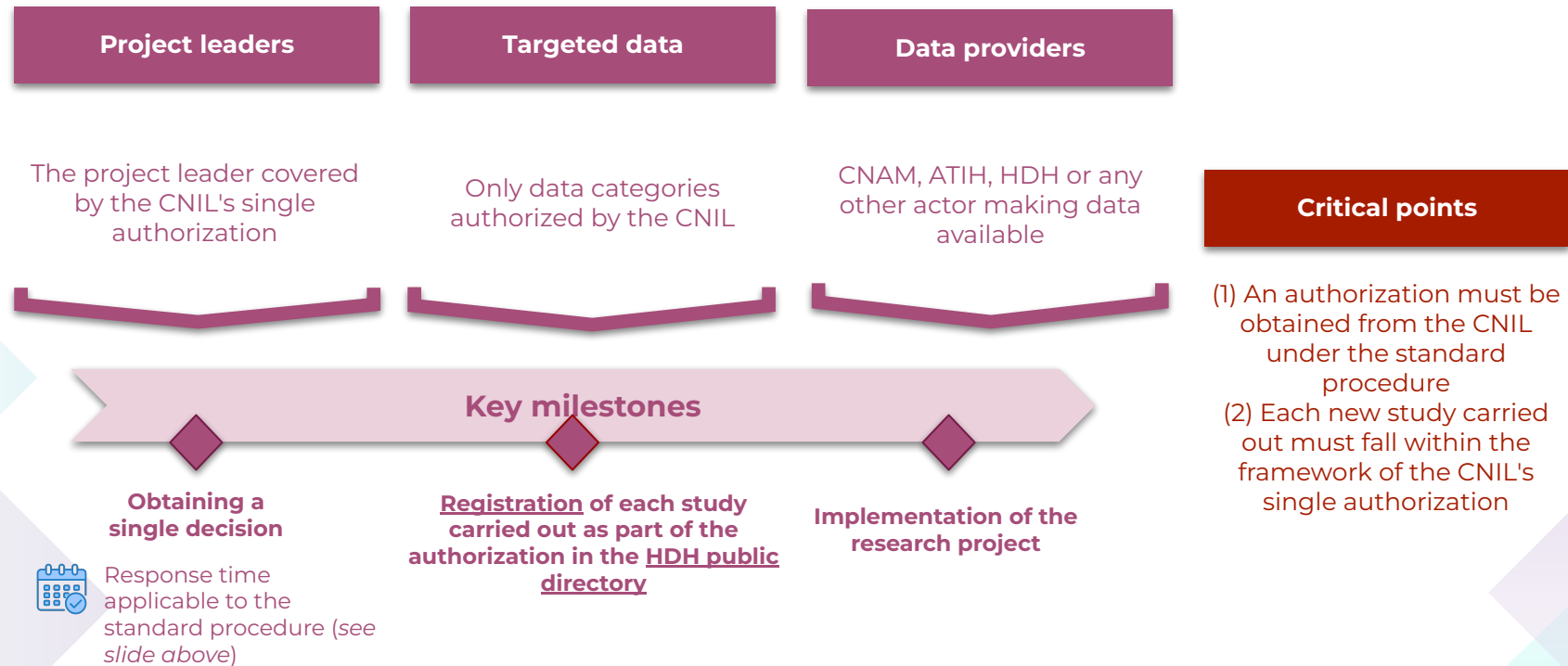
If none of the simplified procedures are applicable to your project, the standard procedure applies: it differs depending on whether the research envisaged is an RIPH or an RNIPH.



To learn more about how to submit a data access request to conduct a RIPH, contact the [CNRIPH](#) or go to the [french Ministry of Health website](#)

To learn more about how to submit a data access request to conduct an RNIPH, go to the [HDH website](#).

# Single decision



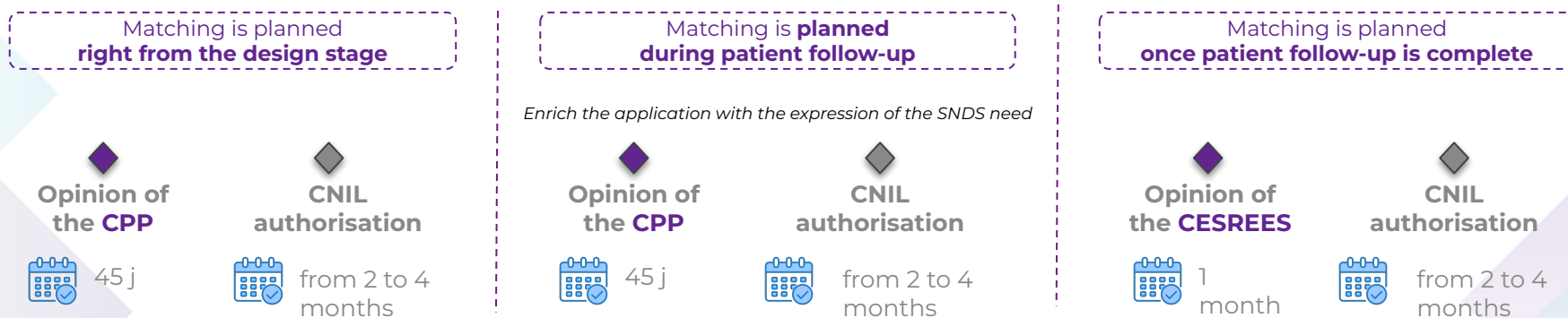
# Special cases of mixed research

## 1 Definition of a mixed research

Mixed research refers to studies that simultaneously include a-RIPH component and a component involving the matching of the data collected within this framework and other data, in particular those from the SNDS main database.

In the case of mixed research (SNDS main database or other sources), the committee to be mobilised to access the data depends on the stage of the study at which the matching is considered (*i.e., from the outset, during or after the follow-up of individuals*).

## 2 The three scenarios and the associated regulatory procedures:



Whichever committee decides on the matter, **the data controller must ensure that individuals are individually informed of the data match with the relevant source.**

## Example of a study covered by MR-004 and the standard procedure

**MR-004**

### *Purpose*

Research into the care of people with multiple sclerosis.

### *Objective*

Analysing the impact of the coronavirus on the care of people with multiple sclerosis.

### *Data sources*

Medical records of health establishments taking part in the research

### *Variables used*

Health data, quality of life data, date of birth

### *Data protection*

Informing people individually and collectively

## Example of a study covered by MR-004 and the standard procedure

**Standard  
procedure**

### Purpose

Research into the care of people with multiple sclerosis.

### Objective

Analysing the impact of the coronavirus on the care of people with multiple sclerosis.

### Data sources

Medical records from participating health establishments **matched with Cépidc data**

### Variables used

Health data, quality of life data, date of birth

### Data protection

Informing people individually and collectively

## Example of a study covered by MR-004 and the standard procedure

**Standard  
procedure**

**Purpose**

Research into the care of people with multiple sclerosis.

**Objective**

Analysing the impact of the coronavirus on the care of people with multiple sclerosis.

**Data  
sources**

Medical records of health establishments taking part in the research

**Variables  
used**

Health data, quality of life data, date of birth, **NIR**

**Data  
protection**

Informing people individually and collectively

## Example of a study covered by MR-004 and the standard procedure

**Standard  
procedure**

**Purpose**

Research into the care of people with multiple sclerosis.

**Objective**

Analyse the impact of the coronavirus on the care of people with multiple sclerosis.

**Data  
sources**

Medical records of health establishments taking part in the research

**Variables  
used**

Health data, quality of life data, date of birth

**Data  
protection**

**Exemption from the obligation to individually inform individuals lost to follow-up.**

## Example of a study covered by MR-007/MR-008 and the standard procedure

**MR-007 or  
MR-008**

**Purpose**

Research into the care of people with multiple sclerosis.

**Objective**

Analysing the impact of the coronavirus on the care of people with multiple sclerosis.

**Data  
sources**

**Data from the SNDS main database for the period 2018 to 2023**

**Variables  
used**

Outpatient, hospital and SI-DEP treatment data

**Data  
protection**

**Collective information for individuals**



## Example of a study covered by MR-007/MR-008 and the standard procedure

**Standard  
procedure**

**Purpose**

Research into the care of people with multiple sclerosis.

**Objective**

Analysing the impact of the coronavirus on the care of people with multiple sclerosis.

**Data  
sources**

**Data from a register matched with data from the SNDS main database over the period 2018 to 2023**

**Variables  
used**

Health data, quality of life data, date of birth

**Data  
protection**

Collective information for individuals

## Example of a study covered by MR-007/MR-008 and the standard procedure

**MR-007 or  
MR-008**

### *Purpose*

Research into the care of people with multiple sclerosis.

### *Objective*

Analyse the impact of the coronavirus on the care of people with multiple sclerosis.

### *Data sources*

**Data from the SNDS main database for the period 2015 to 2025**

### *Variables used*

Outpatient, hospital and SI-DEP treatment data

### *Data protection*

Collective information for individuals

# Open resources: Regulatory procedures



## Toolkits

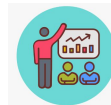
1

[Starter Kit](#) for the standard procedure

[Starter Kit](#) for MR-007 & 008 framework

[Toolkit](#) for the simplified ESND access procedure

[Toolkit](#) for substantial modifications



## Training programs

2

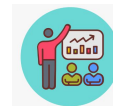
[Training](#) on data access procedures

[Training](#) on MR-007 and MR-008

# Open resources: HDH support



Helping researchers complete their projects



Increase knowledge of the main SNDS database and other data sources

1

[Starter kit](#) on key issues

[Toolkit](#) for the transparency obligation

[Toolkit](#) for information notices to individuals

2

Citizen [training](#) on the SNDS

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

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

Collaborative [documentation](#)

[Support forum](#)

[Public directory](#) of projects

## Partner resources : CNIL

[Form](#) on formalities for theses and dissertations

[Fact sheet](#) on the legal framework for medical research

[Focus on](#) individual and collective information

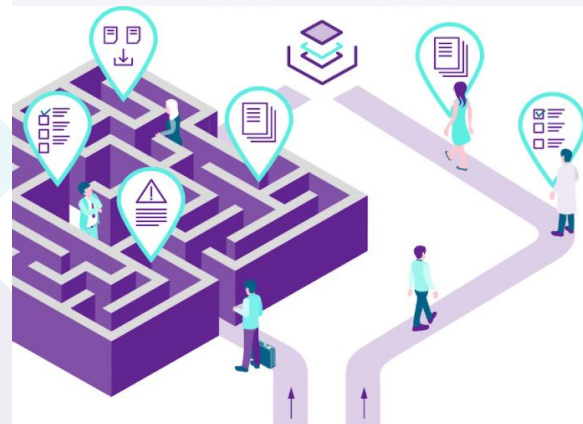
# Appendix

## **Focus on the RNIPH authorisation procedure**

# The HDH helps you with your standard procedure



## Health data



without  
starter kit

with  
starter kit



**The HDH is the single point of contact for data access.** Requests for access to data are made online, on the HDH's dedicated [platform](#).



All the templates and educational documents are made available to project leaders in a [starter kit](#), to guide them through the process.



**The HDH checks that the application is complete** and forwards it to the Ethics and Scientific Committee for assessment (CESREES).

# CESREES assesses the scientific relevance of the project



The CESREES (Ethics and Scientific Committee for Research, Studies and Evaluations in the Health Sector) is **responsible for issuing its opinion on research projects requiring the use of health data**, prior to authorisation by the CNIL.



It is made up of **around twenty members** appointed by decree. It is supported by a network of **external experts** and its secretariat is provided by the HDH.

## The Ethics and Scientific Committee gives its opinion on :

- ✓ Research **objective** and **methodology** ;
- ✓ The **need** to use personal health data ;
- ✓ **Ethical** relevance ;
- ✓ The **scientific quality of** the project ;
- ✓ **The public interest** nature **of the project**.

# The CNIL, the only authority competent to authorise the project



The **Commission nationale informatique & libertés (CNIL)** is an **independent administrative authority** composed of experts in the fields of security, digital technology and the related regulatory framework.



At the request of the project leader, **the HDH submits the access request to the CNIL** for authorisation.



The CNIL's departments **assess the application** and may contact the project leader for any additional information if necessary.

**CNIL.**  
COMMISSION NATIONALE  
INFORMATIQUE & LIBERTÉS



# Glossary (1/3)

**1** A **controlled environment** must meet the following conditions:

- It must have been **approved in accordance with the security guidelines applicable to the SNDS**. This approval, which **must not have expired**, is subject to regular monitoring and is regularly renewed within the deadlines set out in the approval decision.
- It must have been **appraised by the CNIL** as part of a data processing operation that has been expressly authorised by the CNIL. This authorisation must be **less than three years** old.
- An agreement must be drawn up between the data controller and CNAM or the manager of the controlled environment, where applicable.

**2** A **SNDS Subsidiary System** hosts data from the main SNDS database. However, it cannot supply the main database with external data.

## Glossary (2/3)

3



**The public interest** primarily concerns processing carried out by public authorities. It may, however, authorise the implementation of processing operations by private bodies, provided that they pursue a mission of public interest or are endowed with prerogatives of public authority. The public interest mission may in particular be the basis for processing operations aimed at the users of the public authority concerned.

4



**Legitimate interest** concerns processing carried out by private bodies that does not significantly affect the rights and interests of data subjects. The legitimate interest of a project may be presumed if the following 3 conditions are met:

- the interest is manifestly lawful under the law;
- it is sufficiently clear and precise;
- it is real and present for the organisation concerned, and not fictitious.

# Glossary (3/3)

## 5 Distinction between **information notice** (NI) and **consent form** (FC) :

- **Information:** it must be personalised, sincere, honest and intelligible ([HAS guide](#)).
  - **individual:** in principle, information is individual.
  - **collective:** but information can sometimes be collective ([L.1122-1-4 of the CSP](#) referred to in [MR-003](#), [MR-007](#), [MR-008](#), etc.).
- **Consent form (FC):** it formalises both the information provided by the sponsor to the participant and the participant's agreement to take part in the research. It generally follows the information note. It is subject to specific formalities (dated, signed, right to withdraw consent at any time, etc.) and is compulsory before the study begins.
  - [RIPH 1](#): free, informed and written consent
  - [RIPH 2](#): free, informed and express consent (oral or written)
  - [RIPH 3](#): no-objection form

## Acronyms used

**ATIH:** Agence Technique de l'Information sur l'Hospitalisation (French Hospital Information Technical Agency)

**CESREES:** Comité Éthique et Scientifique pour les Recherches, les Études et les Évaluations dans le domaine de la Santé (Ethics 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)

**CPP:** Committee for the Protection of Persons

**ESND:** Échantillon du SNDS (SNDS sample)

**HDH:** Health Data Hub

**MR:** Méthodologie de Référence (Reference Methodology)

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

**RIPH:** Research Involving the Human Subjects

**RNIPH:** Research Not Involving the Human Subjects

**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-Scheme Information System)

## Do you need help?

If, after consulting this guide, you still have questions about the nature of your research or the procedure applicable to it, you can :

- ❖ [Visit our website](#);
- ❖ [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.



[contact@health-data-hub.fr](mailto:contact@health-data-hub.fr)