Resource: ESND Reference Framework

Deliberation No. 2022-124 of 13 October 2022 adopting a reference framework concerning the description and procedural access for processing the national health data system sample (ESND) and the thematic databases known as “datamarts” from the French National Health Insurance Inter-Schemes Information System (SNIIRAM) presenting a low risk of impact on privacy and repealing Deliberation No. 2020-072 of 16 July 2020

The French Data Protection Authority (*Commission nationale de l'informatique et des libertés*),
Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC;
Having regard to the Public Health Code, in particular Articles L. 1461-1 et seq. and R. 1461-1 et seq;
Having regard to Act No. 78-17 of 6 January 1978 as amended on information technology, data protection and civil liberties, in particular Article 66 thereof;
Having regard to Deliberation No. 2020-072 of 16 July 2020 adopting a reference framework concerning the description and procedural guarantees for making available for processing the general sample of beneficiaries (EGB) and the thematic databases known as datamarts from the French National Health Insurance Inter-Schemes Information System (SNIIRAM) presenting a low risk of impact on privacy and repealing Deliberation No. 2019-039 of 11 April 2019;
On the proposal of Ms Valérie PEUGEOT, Commissioner, and having heard the observations of Mr. Benjamin TOUZANNE, Government Commissioner,
Makes the following observations:
The reference framework on the description and procedural guarantees for making available for processing the SNDS data sample (hereinafter ESND) and the thematic databases known as SNIIRAM datamarts to be made available for processing is intended to replace the repository framing the provision of data from the EGB and the thematic SNIIRAM databases known as datamarts established by Deliberation No. 2020-072 of 16 July 2020.
Constituted by the French National Health Insurance Fund (CNAM), the ESND is a random sample grouping together two percent of the people whose data appear in the SNIIRAM mentioned in Article L. 161-28-1 of the Social Security Code.
The ESND contains the following SNIIRAM information:

- Inter-Scheme Healthcare Consumption Datamart, also known as “individual-level beneficiary database”;
- the data contained in the Program of medicalization of the information systems (PMSI) in the fields of medicine, surgery, obstetrics and odontology (MCO), follow-up and rehabilitation care (SSR), Medical data collection for psychiatry (RIM-P) and Medical data collection for home hospitalization (HAD).

The SNIIRAM is also used to create thematic databases of aggregated data known as “datamarts for healthcare expenditure monitoring” (DAMIR) or “datamarts for healthcare supply analysis” (AMOS), as well as management charts for biology and pharmacy. These datasets are included in the scope of this reference framework.
This sample can be used to gain a better understanding of healthcare usage, care pathways and healthcare expenditure among insured persons.
In accordance with the provisions of the third paragraph of Article 66-II of the Data Protection Act, health data sets presenting a low risk of impact on privacy may be made available for processing under conditions defined in advance by a reference framework, without prior authorisation being required.
The Authority points out, as a preliminary matter, that as the ESND data is derived from the SNIIRAM, a component of the main SNDS database, all the legislative and regulatory provisions relating to the SNDS are applicable to the processing of data derived from the ESND, in particular:

- the prohibition on using SNDS data for the purposes described in Article L. 1461-1-V of the Public Health Code (CSP) (prohibited purposes);
- compliance with the security standard applicable to the SNDS provided for in Article L. 1461-1-IV-3° of the CSP;
- the principle of transparency provided for in Article L. 1461-3-II of the CSP.

Decides:
The description and procedural guarantees for making available for processing personal data from the ESND and/or “datamarts” and dashboards from the SNIIRAM, defined by the Commission are as follows:
Processing eligible for a single approval issued by the Health Data Hub:
The conditions of access defined in this reference framework apply to processing carried out for the purposes of research, study or evaluation in the field of health, justified by public interest, and for which only access to ESND data and/or datamarts and dashboards from SNIIRAM is necessary.
Processing operations that meet the following cumulative conditions are eligible for single approval by the Health Data Hub (HDH):

- the processing is carried out within the CNAM’s secure portal;
- there is no cross-referencing of several potential identifiers, as defined by the regulatory provisions applicable to the SNDS;
- the duration of access to the portal does not exceed twenty-four months. This period may

be extended for a maximum of twenty-four months upon substantiated request by the data controller;
- the processing meets one of the following purposes:
- comparative assessment of healthcare provision;
- changes in care practices;
- comparative analyses of healthcare activities;
- description and analysis of pathologies and patient care pathways;
- epidemiological and/or medico-economic studies, including studies to prepare cases for discussions and meetings with the competent authorities and committees, or studies for monitoring purposes;
- feasibility studies for research involving or not involving the human person.

Specific access procedures for certain categories of data controllers:
In order to benefit from these conditions for access to the ESND and datamarts, the following entities are required to use a study office or contract research organization as specified in Article L. 1461-3 of the CSP:

- persons producing or marketing products mentioned in Paragraph II of Article L. 5311-1, of the CSP;
- the organisations mentioned in Paragraph 1 of A and Paragraphs 1, 2, 3, 5 and 6 of B of I of Article L. 612-2 of the Monetary and Financial Code and insurance intermediaries mentioned in Article L. 511-1 of the Insurance Code.

Review by the Health Data Hub for single approval:
The request to the HDH for access to ESND data and datamarts includes:

- the protocol, including justification of public interest, as well as a summary, in accordance with the template provided by the HDH;
- the declarations of interest of the data controller and head of the study office or contract research organization, in relation to the purpose of the studies;
- at the end of the studies, the method and the results obtained with a view to their publication;
- compliance of the recording of the processing and the transmission of the results with the procedures defined by the HDH.

The Health Data Hub makes its decision based on the following elements:

- the justification provided by the data controller to demonstrate the scientific relevance of the project;
- the justification for the historical depth requested concerning ESND data (nine years in addition to the current year or nineteen years in addition to the current year);
- the justification for the potential identifier chosen;
- the objective in the public interest pursued by the processing;

- the duration of access to the CNAM portal for the planned processing, which must be limited to the time required to carry out the research, study or evaluation; and, where applicable, the justification for the request for an extension of this period made by the data controller;
- compliance with the legislative and regulatory requirements applicable to the SNDS;
- the procedures for informing data subjects and enabling them to exercise their rights;
- where applicable, compliance with the data access procedures set out in the reference framework determining the criteria of confidentiality, expertise and independence for study offices and contract research organizations.

Access procedure:
The request for access must be sent to the HDH under the same conditions as those applicable to the submission of applications for authorisation to conduct research, studies or evaluations in the field of health, as provided for in Article 76 of the Data Protection Act.
The HDH shall notify the applicant of its decision within fifteen working days of receiving a complete application. In the absence of a response from the HDH within fifteen working days, the request shall be deemed to have been approved.
The HDH may contact the applicant for further information if necessary. The approval period shall be suspended pending receipt of the additional information.
If the HDH does not consider itself in a position to make a decision on the basis of the information contained in the application, it may decide that the proposed processing is subject to the full procedure, in accordance with the provisions of Articles 66, 72 et seq. of the Data Protection Act, and shall inform the applicant accordingly. With the applicant's agreement, the HDH refers the matter to the CESREES for an opinion and then to the French Data Protection Authority (CNIL) for authorisation.
Information and procedures for exercising rights:
The information provided to data subjects cannot be limited to the registration of the processing operation in the HDH public directory.
In application of the provisions of Article 14-5-b of the GDPR, the data controller may claim an exception to the obligation to provide individual information for the implementation of processing involving exclusively data from the ESND and datamarts.
In this case, they must take appropriate measures to protect the rights and civil liberties as well as the legitimate interests of the data subjects, including by making the information publicly available.
Thus, collective information relating to the study must be posted on the website of the data controller and, where applicable, the study office or contract research organization conducting the study. In addition, other channels may be used to communicate this information (social media, regional media, patient associations, press releases, etc.).
When a data controller carries out several studies using ESND data and datamarts, they must set up a transparency portal containing general information about the SNDS, as well as a specific information note for each study.
These documents must include all the information required under Article 14 of the GDPR.
Transparency:
The legal framework governing the provision of SNDS data is designed to ensure that civil society is informed of how the data is used. This principle of transparency is set out in Article L. 1461-3-II of the Public Health Code (CSP). To this end, access to SNDS data is subject to the data controller providing the HDH with certain information before and after

the studies are carried out. The data controller therefore undertakes to record the studies carried out under this reference framework in the public directory held by the HDH. This recording must be carried out before the start of the studies by the data controller or the person acting on their behalf.
The HDH will send the Commission an annual report on the approvals issued under the conditions described in the context of this reference framework, as well as the characteristics of the processing operations carried out.
Entry into force:
Deliberation No. 2020-072 of 16 July 2020 is repealed.
Processing carried out in accordance with the aforementioned deliberation may continue in accordance with the provisions of that deliberation.
This reference framework, which describes and guarantees the procedures for making ESND data and SNIIRAM thematic databases (known as datamarts) available for processing, presenting a low risk of impact on privacy, will enter into force on the day after its publication in the Official Journal of the French Republic.