EMA/89626/2025
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European Medicines Agency's Data Protection Notice

On the use of SNDS data for the performance of DARWIN EU® studies on incidence and prevalence of pathologies and use of drugs in the French population

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency ("EMA" or "Agency") in the context of the use of SNDS data for the performance of DARWIN EU® studies relating in whole or in part to the incidence and prevalence of pathologies and use of drugs in the French population.

As part of the DARWIN EU® (Data Analysis and Real-World Interrogation Network) network that it coordinates, the European Medicines Agency calls on a number of partners, including the Health Data Hub ("HDH"), to carry out studies of the incidence and prevalence of diseases using data from the SNDS[1] main database.

The DARWIN EU® network aims to promote the use of real-world health data to study the use, safety and efficacy of medicines and vaccines, in order to support better decision-making by the EMA committees.

Information on the use of personal data in DARWIN EU® studies is available below. Each study using SNDS data is also registered in the Health Data Hub's public repository[2] prior to its performance.

1. Who is responsible for processing your data?

1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of the Data Analytics and Methods Task Force is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:
datacontroller.analytics@ema.europa.eu

1.2. Who is the data processor?

The Agency may engage third parties to process data on behalf of the Agency and, in particular, to perform scientific studies.

[1] SNDS stands for "Système National des Données de Santé", meaning "National Health Data System".
[2] Available at: https://www.health-data-hub.fr/projets

The contact details of the data processor are the following:

- Health Data Hub – Plateforme des données de santé, 9 rue Georges Pitard 75015 Paris, France, dpd@health-data-hub.fr

2. Purpose of this data processing

The aim of these studies is to analyse the use, safety and efficacy of medicinal products and vaccines for human use in order to support better decision-making by the EMA with reliable evidence throughout the life cycle of medicinal products.

The Agency performs studies as part of pursuing its public health mission to scientifically evaluate the quality, safety and efficacy of medicinal products, in accordance with its mandate under Regulation (EC) No. 726/2004 and Directives 2001/83/EC and 2001/82/EC.

The public interest of these studies, their scientific quality and their ethical relevance have been confirmed by the Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé (CESREES), which is independent of the data controller.

Finally, in accordance with the French Data Protection Act[3], these studies were authorised by the French Data Protection Authority (i.e. Commission Nationale de l'Informatique et des Libertés, "CNIL") on 28/02/2025. The CNIL is the supervisory authority responsible for monitoring the application of data protection rules in order to protect the fundamental rights and freedoms of individuals with regard to data processing.

2.1. Personal data concerned

The data to be used for the DARWIN EU® studies comes from the French National Health Data System (SNDS), which groups together all data relating to reimbursements for healthcare from the French National Health Insurance system, hospital admissions and medical causes of death.

The data concerned are as follows:

- Patients' socio-demographic, medical and socio-economic characteristics: for example, gender, month and year of birth, month and year of death, département of residence, affiliation scheme, year covered for a long-term condition, pathology mapping, social security scheme, deprivation index for the commune of origin, resident in EHPAD.
- Data relating to the consumption of healthcare in the community: for example, procedures provided (drugs, examinations, medical consultations, etc.), their nature and date of performance;
- Data relating to hospital care consumption: for example, types of unit, length of stay, procedures performed, drugs dispensed, discharge methods, date performed.

All these data will be kept for a period of 3 years from the start of each study.

2.2. Legal basis of the processing

The Agency relies on Article 5(a) and Article 10(2)(i) of Regulation (EU) 2018/17253 to determine, in its capacity as data controller, the means and purposes of the processing of personal data to carry out studies.

[3] La loi « Informatique et Libertés » (i.e. loi nº 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, plus connue sous le nom de loi informatique et libertés)

In line with Article 5(a) of the EUDPR, the processing of the selected SNDS data is necessary for the performance of a task carried out in the public interest. In accordance with Article 57 of Regulation (EC) 726/2004, EMA acting particularly through its committees, performs studies to provide Member States and the European Union institutions with the best possible scientific advice on the use, safety and efficacy of medicinal products and vaccines for human use. Additionally, and in line with Article 10(2)(i) of the EUDPR, the processing of the special categories of personal data held in the selected SNDS data is necessary for EMA for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health and ensuring high standards of quality and safety of medicinal products or medical devices as the performance of studies contributes to informing the decision making of EMA's committees.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of EU

The studies will be performed within the HDH's technological platform, which is hosted in Microsoft's data centres located in the 'France Zone' and certified as a 'Health Data Host'. Due to specific provisions of the contract between HDH and Microsoft, as well as the nature of the management activities of the technological platform, certain technical and monitoring data (which do not include any personal data related to health) may be transferred/shared with operators located outside the European Economic Area. These data transfers are governed by the standard contractual clauses adopted by the European Commission, a copy of which may be obtained from HDH's Data Protection Officer at the following address: dpd@health-data-hub.fr

3. How long do we keep your data?

All these data will be kept for a period of 3 years from the start of each study.

4. Who has access to your information and to whom is it disclosed?

EMA's staff will have no access whatsoever to your personal data. Access to the data will be via a secure workspace for those responsible for carrying out the study, i.e. the people who will be working on the data. More specifically, these are:

- People working at the Health Data Hub, the data processor, who are authorised to access and process the data;
- People working on behalf of the Health Data Hub (e.g. subsequent subcontractors).

5. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.

- **Right to rectification** – You have the right to obtain without undue delay the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

6. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at datacontroller.analytics@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en