



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 May 2024  
EMA/221505/2024

## Data Protection Notice on the study of the “Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV- during the Omicron period”

This data protection notice explains the essential elements of the processing of your personal data by the European Medicines Agency (hereinafter ‘EMA’ or ‘Agency’) for the purpose of performing a study on the ‘Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV- during the Omicron period’ as part of the piloting of the test version<sup>1</sup> of the European Health Data Space (‘EHDS’).<sup>2</sup>

### 1. Who is responsible for processing your data?

#### 1. Who is the data controller?

The European Medicines Agency is ultimately responsible for processing your data in accordance with your data protection rights and freedoms. On behalf of the Agency, the Head of the Data Analytics and Methods Task Force acts as the “Internal Controller” to ensure the lawfulness of the processing of your personal data.

The contact details of the data controller are as follows:

European Medicines Agency - Agence européenne du médicament  
Domenico Scarlattilaan 6,  
1083 HS Amsterdam, THE NETHERLANDS

You can contact the Internal Controller at the following e-mail address:

[datacontroller.analytics@ema.europa.eu](mailto:datacontroller.analytics@ema.europa.eu)

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<sup>1</sup> Plateforme de données de santé, 3 Octobre 2022, *Project de l’espace européen des données de santé : les cinq cas d’usage*, <https://www.health-data-hub.fr/actualites/projet-pilote-de-lespace-europeen-des-donnees-de-sante-les-5-cas-dusage>

<sup>2</sup> Plateforme de données de santé, 18 novembre 2022, *Coup d’envoi officiel pour le pilote de l’Espace européen des données de santé*, <https://www.health-data-hub.fr/actualites/coup-denvoi-officiel-pour-le-pilote-de-lespace-europeen-des-donnees-de-sante>



## **2. Who is data processor?**

The Agency contracted the Health Data Platform ('HDH') to perform the study on behalf of the Agency and, thereby, to process your personal data. The contact details of the Data protection Officer of HDH are as follows:

Plateforme de données de santé - Health Data Hub  
9 rue Georges Pitard  
75015 Paris, FRANCE  
[dpd@health-data-hub.fr](mailto:dpd@health-data-hub.fr)

## **2. Purpose of this data processing**

The purpose of the processing activity is to carry out a scientific study on coagulopathy in COVID-19 patients and people vaccinated against SARS-COV- in France between 2017 and 2023 (during the Omicron period). The Agency performs this study 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.

### **1. Personal data concerned**

As part of this processing operation, the Agency is the data controller for the processing of personal data already collected from you via the French National Health Data System (SNDS). The SNDS holds data captured by the French national healthcare reimbursement system as well as administrative and medical data relating to hospitalisations. Your personal data has been pseudonymised and stored in a dedicated workspace on the technology platform managed by the Health Data Hub. This workspace is separate from the SNDS where the personal data originally collected from you remain stored.

Your pseudonymised personal data may include the following:

- Pseudonymised patient number
- General information about the patient (age, gender, place of residence, socio-economic status)
- Medicines prescribed
- Data relating to vaccination against COVID-19
- Data on diagnoses and co-morbidities
- Data relating to hospitalisations (date, symptoms, diagnoses, medical or surgical procedures, care pathway)
- Data relating to deaths (cause and date of death)

### **2. Legal basis of the processing**

The Agency relies on Article 5(a) and Article 10(2)(i) of Regulation (EU) 2018/1725<sup>3</sup> to determine, in its capacity as data controller, the means and purposes of the processing of personal data to carry out the study.

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<sup>3</sup> Regulation (EU) 2018/1725 of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

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. EMA's public interest is twofold. Firstly, as part of the pilot, EMA and HDH will gather insights in the processing of electronic health data for secondary use in accordance with the purposes set out in Article 34 of the Proposal for a European Health Data Space. Using different data sources holding personal data related to health will be instrumental in understanding the feasibility of the implementation of the EHDS. Secondly, in accordance with Article 57 of Regulation (EC) 726/2004, EMA acting particularly through its committees, will perform a pharmacoepidemiological study on COVID-19 vaccines to provide Member States and the European Union institutions with the best possible scientific advice on the safety and efficacy of these vaccines.

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 the study will contribute to informing the decision making of EMA's committees.

### **3. *Transfer of personal data outside of the EU***

The study 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](mailto:dpd@health-data-hub.fr)

### **3. How long do we keep your data**

Your personal data will be stored for five years in the dedicated workspace of the technology platform managed by HDH. After five years, the workspace and the personal data it contains will be deleted.

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

Data stored in the workspace will be processed internally by HDH staff to perform the study. The European Medicines Agency staff will not have access to your personal data in any way.

The aggregated results of the study will not contain any personal data. They may be shared with third parties, such as members of the Agency's scientific committees, and published on the Agency's website.

### **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](http://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](http://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](mailto:datacontroller.analytics@ema.europa.eu) or the **EMA Data Protection Officer** at [dataprotection@ema.europa.eu](mailto: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](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)