



13 May 2024
EMA/228382/2024

Records of data processing activity (public)

Name and reference number of processing operation: Study of the "Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV- during the Omicron period".

1.	Last update of this record, version number:	Version 1
2.	Reference number:	TDA-011
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of the Data Analytics and Methods Task Force Contact: datacontroller.analytics@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	Plateforme de données de santé (Health Data Hub ; « HDH ») 9 rue Georges Pitard 75015 Paris, FRANCE dpd@health-data-hub.fr
7.	Purpose of the 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.



8.	Description of categories of persons whose data EMA processes and list of data categories	<p>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.</p> <p>Your pseudonymised personal data may include the following:</p> <ul style="list-style-type: none"> • Patient identifier • 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)
9.	Time limit for keeping the 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.
10.	Recipients of the data	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'.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	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
12.	General description of security measures, where possible.	The project follows a global security approach (e.g. performance of a DPIA, a risk analysis of the project, approval of the project by management, definition of procedures for the management of security incidents and data breaches) and

		makes it possible to control the risks related to the performance of the study.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	<p>Details concerning the processing of your personal data are available on the Agency’s website at:</p> <p>https://www.ema.europa.eu/en/about-us/data-protection-privacy</p> <p>Here you may find the data protection notice regarding this specific data processing operation as well.</p>