10 March 2023
EMA/110797/2023

Records of data processing activity regarding the European Union (EU) Metadata Catalogue(public)

1.	Last update of this record, version number:	01/03/2022, version 1
2.	Reference number:	EMA-TDA-008-RoPA
3.	Name and contact details of controller:	European Medicines Agency (EMA) 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)	Not applicable
6.	Name and contact details of processor (where applicable)	The Agency may engage third parties to process data on behalf of the Agency and, in particular, to carry out the following activities: collection, validation and data management of the metadata of Real World Data Sources, Institutions and Networks in the European (EU) Metadata Catalogue. The Agency may engage third parties to support the: • development and maintenance of EU Metadata Catalogue functionalities; • collection, management and validation of the metadata information that EU Metadata Catalogue contains; • provision of system and data support to EU Metadata Catalogue users. Contact details of the EMA processors can be made available to the data subjects upon request.
7.	Purpose of the processing	The EU Metadata Catalogue is designed to:

		• facilitate the discoverability of data sources to generate adequate evidence for regulatory purpose; • help regulators, researchers and pharmaceutical companies to identify data sources suitable to address research questions, based on the so-called 'FAIR' (findable, accessible, interoperable and reusable) data principles; • improve the ability of the aforementioned stakeholders to assess evidence from real-world data sources. The purpose of this data processing activity is to collect and present in a single catalogue information including contact details about data sources, institutions and networks to foster their discoverability by researchers and potential study funders. Where available, the catalogue may also include links to relevant webpages or supporting documentation related to the governance of the data source or to describe the mapping of the data source to a Common Data Model (CDM). This information is to support the identification of appropriate data sources for conducting pharmacoepidemiological and pharmacovigilance studies. All information contained in the EU Metadata Catalogue is provided voluntarily and maintained by listed institutions, networks, data providers, registry holders and other types of organisations. It is the responsibility of each individual entity to enter and maintain the required information and to keep the information up to date. In preparation of the go-live of the EU Metadata Catalogue EMA the data processor is: • migrating the information contained in the ENCePP Resources database to the EU Metadata Catalogue; • enriching the information contained in the ENCePP Resources database in liaison with the contact points of the organisations listed in the ENCePP Resource Database; • collecting (via MS Excel files) metadata information related to additional data sources not included in the ENCePP Resources database.

8.	Description of categories of persons whose data EMA processes and list of data categories	Contact name and e-mail address of representatives from research organisations, institutions, networks and data sources, including patient registries.
9.	Time limit for keeping the data	Personal data is kept by EMA until: • it is either updated by the data owner; or • a request for removal is received.
10.	Recipients of the data	The EU Metadata Catalogue is available to the public. During the development of the EU Metadata Catalogue, the metadata information collected via Excel may be also shared with the data processor and other interested parties.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Not applicable.
12.	General description of security measures, where possible.	The EU Metadata Catalogue is kept in a secure electronic environment designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored. Data may only be changed or deleted by authorised persons using a username and password. Authorisation is given at senior management level and based on business needs.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement You may find the data protection notice regarding this specific data processing operation as well at: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-european-union-eu-metadata-catalogue_en.pdf