13 February 2024
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European Medicines Agency

Records of data processing activity regarding the European Union (EU) HMA-EMA Catalogue of real-world data sources (public)

1.	Last update of this record, version number:	08/02/2024, version 2
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 information of data sources, institutions and networks in the HMA-EMA Catalogue of real-world data sources. The Agency may engage third parties to support the: • development and maintenance of functionalities; • collection, management and validation of the information that HMA-EMA Catalogue of real-world data sources contains; • provision of system and data support to HMA-EMA Catalogue of real-world data sources users.

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		Contact details of the EMA processors can be made available to the data subjects upon request.
7.	Purpose of the processing	The HMA-EMA Catalogue of real-world data sources 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 these 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 including institutions and networks. The objective is to foster the discoverability of data sources for conducting pharmacoepidemiological and pharmacovigilance studies by researchers and potential study funders. Where available, the HMA-EMA Catalogue of real-world data sources may include links to relevant webpages or supporting documentation related to the governance of the data source and/or to describe the mapping of the data source to a Common Data Model (CDM). All information contained in the HMA-EMA Catalogue of real-world data sources 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 HMA-EMA Catalogue of real-world data sources the following steps are to take place: • migrating the information contained in the ENCePP Resources database to the HMA-EMA Catalogue of real-world data sources; • 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) 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	The Agency processes personal data contained in the HMA-EMA Catalogue of real-world data sources as follows: the contact's name and e-mail address of representatives from research organisations, institutions, networks and data sources, including patient registries. The Agency also processes personal data of registered users of the HMA-EMA Catalogue of real-world data sources, also referred to as editors, authors and co-authors in the context of the catalogue (hereafter referred to as "users"). Users are registered using the EU-Login1 authentication service of the European Commission. Personal data may include the following: Names and contact details of (co-) authors/users, who are inserting and managing data source, institution, and network records, in the catalogues.
9.	Time limit for keeping the data	Personal data is kept in the HMA-EMA Catalogue of real-world data sources until: • it is either updated by you in your role as data source holder, institution or network; or • a request for removal is received by EMA. The retention period for logged revisions is 5 years and reviewed annually by 15 February. The Excel files collected during the development/establishment phase of the HMA-EMA Catalogue of real-world data sources will be kept for a period of 12 months from the date of the go-life.
10.	Recipients of the data	The information provided in the HMA-EMA Catalogue of real-world data sources which is registered on a voluntary basis is made available to the public. Personal data of registered users of the HMA-EMA Catalogue of real-world data sources (e.g., editors, authors and co-authors in the context of the catalogues) is shared with EMA staff managing the HMA-EMA Catalogue of real-world data sources and data processor.

[1] IAM Privacy Statement (europa.eu)

		During the development/establishment of the HMA-EMA Catalogue of real-world data sources, the information collected via Excel files may be also shared with the data processor.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Register intended for consultation by the public
12.	General description of security measures, where possible.	The HMA-EMA Catalogue of real-world data sources 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