



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2023
EMA/114219/2023

European Medicines Agency's Data Protection Notice For the European Union (EU) Metadata Catalogue

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the collection/maintenance and public dissemination of metadata information on Real World Data Sources, Institutions and Networks via the European Union (EU) Metadata Catalogue.

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 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 carry out the following activities: collection, validation and data management of the metadata of data sources, institutions and networks in the 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.

2. Purpose of this data processing

The EU Metadata Catalogue is designed to:

- facilitate the discoverability of data sources to generate adequate evidence for regulatory purpose;

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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- 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.

2.1. Personal data concerned

The Agency processes personal data contained in the EU Metadata Catalogue with regards to the contact name and e-mail address of representatives from research organisations, institutions, networks and data sources, including patient registries. These entities voluntarily register their data sources in the EU Metadata Catalogue by filling-in the form online or via Excel forms sent to the EMA. It is their responsibility to keep this information up-to-date. Information may be edited at any time by the entities concerned.

Registration in the EU Metadata Catalogue implies a commitment to review and update the entries regularly, and, as a minimum, at least every twelve (12) months.

2.2. Legal basis of the processing

When you provide your data, you consent to the processing of that data in accordance with this Data Protection Notice in accordance with Article 5(d) of Regulation (EU) 2018/1725. You may opt-out from the processing at any time by sending an email to datacontroller.analytics@ema.europa.eu. In your email please state what is the personal data that you want to exclude and what is the actual

processing activity that you do not want EMA to carry out on your data. You also have the right to withdraw your consent later at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

3. How long do we keep your data?

Personal data is kept by EMA until:

- it is either updated by the data source, institution or network; or
- a request for removal is received.

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

The data registered on a voluntary basis is made 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.

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 withdraw consent** – You have the right to withdraw your consent to the processing of your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.

Please note that if you withdraw your consent, the Agency may not be able to provide certain services to you. EMA will advise you if this is the case at the time you withdraw your consent.

- **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 portability** - Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.
- **Right not to be subject to automated decision making** – You have the right to not to be subject to a decision based solely on automated processing if such decision has legal effect on you.

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