



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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European Medicines Agency

## European Medicines Agency's Data Protection Notice For the HMA-EMA Catalogue of real-world data sources

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 information on real-world data sources, institutions and networks via the HMA<sup>1</sup>-EMA Catalogue of real-world data sources (hereafter referred to as HMA-EMA Catalogue real-world data sources).

### 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](mailto: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 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 of the HMA-EMA Catalogue of real-world data sources;
- collection, management and validation of the information that the HMA-EMA Catalogue of real-world data sources contains;

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<sup>1</sup> Heads of Medicines Agencies: About HMA



- provision of system and data support to the HMA-EMA Catalogue of real-world data sources users.

The Agency engaged the following processors:

- European Commission Directorate General for Informatics (DG DIGIT)
- IQVIA Nederland
- University Medical Center Groningen, Genomics Coordination Center, Molgenis

## **2. Purpose of this data 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 about data sources including institutions and networks and contact details. 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.

Additionally, the email address of data subjects may be processed if they subscribe to receive email notifications on the update of data studies.

## 2.1. Personal data concerned

The Agency processes the following personal data:

- **Personal data contained in the HMA-EMA Catalogue of real-world data sources.** This entails the name and professional e-mail address of the contact person of representatives from research organisations, institutions, networks and data sources, including patient registries. These entities voluntarily register their data sources in the HMA-EMA Catalogue of real-world data sources by filling-in the online form or via Excel forms sent to the EMA.

Registration in the HMA-EMA Catalogue of real-world data sources implies a commitment by the respective entities who provide the data to review and update the entries regularly, and, as a minimum, at least every twelve (12) months. It is responsibility of these entities to keep this information up-to-date. Updates can be performed at any time as deemed necessary.

- **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-Login<sup>2</sup> 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 a data source, institution, and network records in the catalogues.
- **Personal data of data subjects subscribing to get notifications of changes made to data sources:**
  - Email address

## 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(1)(d) of Regulation (EU) 2018/1725 i.e., the data subject has given consent to the processing of his or her personal data for one or more specific purposes. These purposes are set out in section 2 of this data protection notice.

You may opt-out from the processing at any time by sending an email to [datacontroller.analytics@ema.europa.eu](mailto: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 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 is reviewed annually by 15 February.

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<sup>2</sup> [IAM Privacy Statement \(europa.eu\)](#)

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-live.

The email address of data subjects who subscribed to receive email notifications is kept until they unsubscribe or after a period of 3 years after they subscribed if they do not confirm their wish to keep receiving email notifications. This confirmation request is sent within 2 months before the end of the 3-year period.

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

The EMA Catalogue of real-world data sources constitutes a register necessary to provide information to the public and which is open to consultation by the public as defined by Article 50 of Regulation (EU) 2018/1725.

Noting that the information provided in the HMA-EMA Catalogue of real-world data sources is registered on a voluntary basis, the legality of its publication online is based on Article 50(1)(a) of Regulation (EU) 2018/1725, i.e. "the data subject has explicitly consented to the proposed [publication online], after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards" in certain third countries from which the HMA-EMA Catalogue of real-world data sources can be accessed.

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 processors.

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 processors.

## 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 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.

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)