13 February 2024
EMA/60093/2024
European Medicines Agency

European Medicines Agency's Data Protection Notice

For the HMA-EMA Catalogue of real-world data studies

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 HMA[1]-EMA Catalogue of real-world data studies.

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 HMA-EMA Catalogue of real-world data studies.

The Agency may engage third parties to support the:

- development and maintenance of functionalities of the HMA-EMA Catalogue of real-world data studies;
- collection, management and validation of the information that the HMA-EMA Catalogue of real-world data studies contains;
- provision of system and data support to the users of the HMA-EMA Catalogue of real-world data studies.

Contact details of the EMA processors can be made available to the data subjects upon request.

[1] Heads of Medicines Agencies: About HMA

2. Purpose of this data processing

The HMA-EMA Catalogue of real-world data studies is enhancing and replacing the European Union electronic register of post-authorisation studies (EU PAS Register®).

The purpose of these data processing activities is to:

- ensure compliance with legal requirements set out in Union pharmacovigilance legislation[2], in particular Articles 107n-q of Directive 2001/83/EC, and GVP Module VIII.B.2[3],
- increase transparency,
- reduce publication bias,
- promote the exchange of information and facilitate collaboration among stakeholders including academia, regulatory bodies, and pharmaceutical companies.

2.1. Personal data concerned

The HMA-EMA Catalogue of real-world data studies contains information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available. As part of the HMA-EMA Catalogue of real-world data studies, the Agency processes personal data within the following categories:

- **Personal data connected to the study**, which may include the following:
    - Names and contact details of primary lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study.
    - Documents uploaded to the database which may contain contact details and names of authors and investigators. In principle, these documents hold only aggregated results and do not contain personal data related to study participants/ patients (e.g., study protocols and reports) in accordance with the Good Practice Guide.
    - Documents uploaded to the database, in particular relating to 'ENCePP Seal' studies, which may contain names and contact details of researchers and other individuals involved in the performance of the study (e.g. declaration of interest, checklists, declaration on compliance with the ENCePP Code of Conduct, composition of steering group/observers).
- **Personal data of registered users of the HMA-EMA Catalogue of real-world data studies**, 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[4] authentication service of the European Commission.
  Personal data may include the following:
    - Names and contact details of editors, authors and co-authors, who are inserting and managing study records, in the catalogues.

[2] EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use
[3] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-viii-post-authorisation-safety-studies-rev-3_en.pdf
[4] IAM Privacy Statement (europa.eu)

Data subject	Personal data processed	Recipient(s)
Personal data connected to the study • Primary lead investigators conducting the study	Names	Published online
• Contact persons for scientific or public enquiries relating to a particular study	Names and contact details	Published online
• Data subjects who are researchers or other individuals involved in the performance of the study and whose personal data is found in documents uploaded to the catalogue (e.g. declaration of interest, checklists, declaration on compliance with the ENCePP Code of Conduct, composition of steering group/observers).	Names and contact details	Published online
Personal data of registered users of HMA-EMA Catalogues (e.g., editors, authors and co-authors in the context of the catalogues) Users are registered using the EU-Login[5] authentication service of the European Commission.	Names and contact details of users	EMA staff managing the HMA-EMA Catalogue and EMA's data processors as applicable

It is the responsibility of the registered study editor, primary lead investigator and/or marketing authorisation holder to provide information about each study they register and to keep it up to date. Information, including personal data, may be edited at any time.

Registration in the HMA-EMA Catalogues of real-world data studies implies a commitment to keep the study record, including milestones reached, up to date at all times. As stated in GVP Module VIII, it is

[5] https://wikis.ec.europa.eu/display/NAITDOC/EU+Login+-+European+Commission+Authentication+Service

recommended that changes should be made within two weeks following the date of the amended protocol at the latest.

2.2. Legal basis of the processing

The processing of personal data is necessary for the performance of a task carried out by the Agency in the public interest as mandated by:

- Article 57(1)(c) of Regulation (EC) No 726/2004 in relation to the safe and effective use of medicinal products authorised in the Union;
- Article 26(1)(h) of Regulation (EU) No 726/2004 which requires the Agency, in collaboration with the Member States and the Commission, to set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised in the Union; and
- Chapter VIII.B.2. Study registration of the Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (latest version)[6] which sets out the requirements to register imposed and non-imposed studies in the EU PAS Register. The format of protocols, abstracts and final study reports for non-interventional post-authorisation safety studies are defined by Article 38 of the Commission Implementing Regulation (EC) No 520/2012.

By means of the HMA-EMA Catalogue of real-world data studies made available through an online portal, the Agency publishes protocols and abstracts of results of the post-authorisation safety studies[7].

Therefore, the processing is lawful under Article 5(1)(a) of Regulation (EU) 2018/1725 and is justified on the grounds of public interest.

3. How long do we keep your data?

Information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available as well as general contact details of lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study is maintained for the duration of the operation of the HMA-EMA Catalogue of real-world data studies. This is to provide an important public resource for scientific research with a large and coherent data pool covering a wide range of medicinal products and studies.

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

See the column "Recipient(s)" in the table under section 2.1. Personal data concerned.

5. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

[6] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-viii-post-authorisation-safety-studies-rev-3_en.pdf
[7] Post-authorisation studies referred to in Articles 107n and 107p of Directive 2001/83/EC

[1]EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use

- **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 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.

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 and Data Protection 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

[1]EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use