9 April 2020
EMA/471904/2019

European Medicines Agency's Privacy Statement - European Union electronic Register of Post-Authorisation Studies (EU PAS Register)

The EU PAS Register®[1] is a publicly available database to provide a register of non-interventional post-authorisation studies (PAS).
This Privacy Statement 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 European Union electronic Register of Post-Authorisation Studies (EU PAS Register).

1. Who is responsible for your data?

1.1. Who is the data controller?

The European Medicines Agency (hereafter "the Agency") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of the Agency, the Head of the Data Analytics and Methods Task Force is appointed as a 'Data Controller' to ensure the lawful conduct of this processing operation.

Contact details: encepp_secretariat@ema.europa.eu.

2. Purpose of this data processing

The EU PAS Register® (http://www.encepp.eu/encepp_studies/indexRegister.shtml) is a publicly available register of non-interventional post-authorisation studies (PAS).

The purpose of this data processing activity is to:

- ensure compliance with legal requirements set out in Union pharmacovigilance legislation[2],
- increase transparency,
- reduce publication bias,

[1] (http://www.encepp.eu/encepp_studies/indexRegister.shtml)
[2] EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use

- promote the exchange of information and facilitate collaboration among stakeholders, including academia, sponsors and regulatory bodies.

The EU PAS Register database contains information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available as well as contact details of lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study.

2.1. Personal Data concerned

As part of the EU PAS Register, the Agency processes personal data submitted by primary lead investigators or their representatives, who perform non-interventional post-authorisation studies (PAS). This 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 pseudonymised personal data (e.g., study reports).
- 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 study (e.g. declaration of interest, checklists, declaration on compliance with the ENCePP Code of Conduct, composition of steering group/observers).

It is the responsibility of the primary lead investigator and/or marketing authorisation holder to enter the information and to keep the information up-to-date. Information may be edited at any time.

Registration in the EU PAS Register 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 recommended that changes should be made within 2 weeks following the date of the amended protocol at the latest.

Pseudonymisation of personal data should follow the principles set out in the "External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use"[3].

2.2. Legal Basis

Article 26(1)(h) of Regulation (EU) No 726/2004 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. By means of that portal, the Agency shall make public protocols and public abstracts of results of the post-authorisation safety studies[4].

The processing of personal data is necessary for the performance of a task carried out by Agency in the public interest 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. Therefore, the processing is lawful under Article 5(a) of the Regulation (EU) 2018/1725 and is justified on the grounds of public interest.

[3] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-1.pdf
[4] Post-authorisation studies referred to in Articles 107n and 107p of Directive 2001/83/EC

In addition to the above, the processing of the personal data is also in accordance with Article 5(d) of Regulation (EU) No 2018/1725 where the data is directly submitted by the person concerned ("data subject") and therefore processing is also based on the consent of the data subject.

Article 38 of the Commission Implementing Regulation (EC) No 520/2012 defines the format of protocols, abstracts and final study reports for non-interventional post-authorisation safety studies.

Chapter VIII.B.2. Study registration of the Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev. 3)[5] sets out the requirements to register imposed and non-imposed studies in the EU PAS Register. To support transparency on PAES that are outside the scope of Directive 2001/20/EC, study information (including for studies conducted outside the EU) should be also made available in the EU PAS Register[6].

3. How long do we keep your data for?

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 an indefinite period in the EU PAS Register. This is to provide for 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?

The data collected is processed internally by staff within the EMA Task Force responsible for maintaining the EU PAS Register.

The database is available to the general public and searchable. It is published on the ENCePP website (www.encepp.eu).

5. Your data protection rights

Data subjects (i.e. the individuals whose personal data is processed in accordance with the above) have the following rights:

- **Right to be informed** – This Privacy Statement provides information on how EMA collects and uses your personal data.
- **Right to access** – Data subjects have the right to access their personal data. You have the right to request and obtain a copy of the personal data held by the Agency, based on the principles set out above.
- **Right to rectification** – Data subjects have the right to obtain without undue delay the rectification of inaccurate personal data concerning him or her, based on the principles set out above.

[5] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-viii-post-authorisation-safety-studies-rev-3_en.pdf
[6] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/post-authorisation-efficacy-studies-questions-answers

- **Right to erasure** – Data subjects have generally the right to require the Agency to delete or stop processing their data, for example where the data is no longer necessary for the purposes of processing. In certain instances, your data may be kept to the extent it is necessary, for example for compliance with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- In cases where the right to erasure is requested and granted to a data subject, data may be kept if it has undergone an appropriate process of anonymisation.
- **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 object** – Data subjects have the right to object to the processing of personal data on grounds related to the data subject's particular situation. This relates to the processing of the data's subjects personal data by the Agency for the performance of a task in the public interest (without consent of the data subject or another lawful basis).

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 privacy 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 Privacy Statement or the general EMA Privacy Statement, please contact encepp_secretariat@ema.europa.eu.

Data subjects may lodge a complaint with the **EMA Data Protection Officer**: 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