



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency privacy statement for Enpr-EMA network database

The European Medicines Agency (hereinafter “EMA” or “Agency”) is committed to respect the right to data protection of individuals. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725¹ (hereinafter “Regulation”).

This Privacy Statement explains how the Agency collects and uses personal data for purposes related to the European network of paediatric research at the EMA (Enpr-EMA) database in accordance with the Agency’s data protection obligations under the Regulation.

1. Who is the data controller?

The Agency is ultimately responsible for complying with Regulation (EU) 2018/1725. Internally, the Head of Human Medicines Research and Development Support Division has been appointed to act as the data controller. Should you wish to get in touch with the Data Controller, please contact enprema@ema.europa.eu

2. Purpose of processing

On the self-assessment form² submitted by networks in order to become a member of Enpr-EMA, we collect contact details of their appointed representatives and other contact persons. Such data will be entered into the Enpr-EMA network database and made available to the public via this database. We use the personal information of the contact persons of the networks to provide information on research networks and centres with recognised specific expertise in the performance of studies in the paediatric population to relevant stakeholders who are involved and/or interested in identifying research networks for paediatric clinical trials in Europe (e.g. pharmaceutical companies, investigators, patients/parents) via the Enpr-EMA network database.

¹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, Available: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1725>

² Form available here: http://enprema.ema.europa.eu/enprema/images/Self_Assessment_PDF_Form_v3.pdf



3. What personal information do we collect and through which technical means?

3.1. Personal Data concerned

The self-assessment form submitted by networks in order to become a member of Enpr-EMA, contains basic personal information about the networks' nominated contact persons, such as name, surname, phone number, e-mail and postal address.

3.2. Legal Basis

The European network of paediatric research at the EMA (Enpr-EMA) was developed by the European Medicines Agency in accordance with Article 44(1) of Regulation (EC) No 1901/2006. Accordingly, this processing of personal data is necessary for the performance of a task carried out by the Agency in the public interest mandated by Article 44 of Regulation (EC) No 1901/2006. Therefore, the processing is lawful under Article 5(a) of the Regulation (EU) 2018/1725 and is justified on the grounds of public interest.

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.

For personal data of third-parties, for example, further contact persons provided in the self-assessment form (i.e. when the data is not directly submitted by the person concerned) the person submitting the self-assessment form declares, by submitting the form, that all personal data are provided in compliance with applicable data protection legislation.

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

Personal data submitted in the self-assessment form is processed (e.g. entered into the EnprEMA network database, amended when necessary) by authorised staff within the Product Development Scientific Support Department of EMA (hereinafter: Enpr-EMA secretariat). Personal data of the contact persons as provided in the self-assessment form are made accessible to the general public on the external website of the EnprEMA network database³.

5. How long do we keep your data?

Your personal data will remain in the Enpr-EMA network database until the Enpr-EMA secretariat is informed of changes to the contact person(s), that the registered network is no longer active or wishes to withdraw its membership or that you wish to withdraw your consent regarding this data processing.

When the Enpr-EMA secretariat is notified of the above, we will securely dispose of your personal data in accordance with the applicable legislation.

6. How do we protect and safeguard your information?

The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data. The Agency takes all the necessary measures to ensure the maximum safety and security of personal data held.

³ Available: <http://enprema.ema.europa.eu/enprema/index.php>

Information provided in self-assessment forms, is recorded in a secured and protected database hosted by the EMA, the operations of which abide by the EMA security policy. The database is not accessible from outside the EMA; nevertheless its content is published as explained in the website.⁴ Inside the EMA the database can only be accessed using a user ID and password. Access to the application is via a non-encrypted connection using the normal http protocol.

7. 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 *withdraw consent* – You have the right to withdraw your consent at any time where EMA is relying on consent to process your personal data. The withdrawal of your consent will not affect the lawfulness of processing based on consent before its withdrawal.
- Right to *be informed* – This Privacy Statement explains how EMA collects and uses your personal data
- Right to *access* – You have the right to access your personal data, i.e., request and obtain a copy of the personal data held by EMA.
- Right to *rectification* – You have the right to obtain the rectification or completion of inaccurate or incomplete personal data.
- Right to *erasure* – You have the right to request EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing.

These rights can be exercised in accordance with the provisions of Regulation (EC) 2018/1725. More detailed information concerning your rights is available in the EMA General Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement.

8. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or that it is not carried out in compliance with this Privacy Statement or the EMA General Privacy Statement, please feel free to contact the Data Controller or the EMA Data Protection Officer.

The contact details of the **Data Controller** are the following: enprema@ema.europa.eu

The contact details of the **Data Protection Officer** are the following: dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor**:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en

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Declaration in the self-assessment form:

By submitting the self-assessment form you confirm that:

- you have read and understood the privacy statement provided,
- you consent to the processing of your personal data as explained therein, and
- regarding personal data of third persons included in your submission you have authorisation to submit such data and you provide this data in compliance with applicable data protection legislation.

⁴ <http://enprema.ema.europa.eu/enprema/index.php>