

10 January 2019 EMA/421890/2018 Rev.1

# European Medicines Agency data protection statement for **Enpr-EMA network database**

### 1. Purpose of processing

The purpose of the present data processing activity is 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.

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

#### 2.1. Identification Data

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

### 2.2. 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.

The legal basis for the processing of personal data in this specific context is your consent, in accordance with <u>Regulation (EU) 2018/1725 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. For personal data of third-parties such as individuals other than the network's nominated main contact person (e.g. further contact persons) that are submitted in the context of the self-assessment form, you declare that you have obtained the adequate consent as to this processing.</u>

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5550 Send a question via our website www.ema.europa.eu/contact



An agency of the European Union

C European Medicines Agency, 2019. Reproduction is authorised provided the source is acknowledged.

#### 2.3. Technical information

The Enpr-EMA network database will make publicly available on the EMA website the following data:

- Network identification and contact details
- Network description (including size of the network)
- Research experience and ability
- Scientific competencies and capacity to provide expert advice
- Quality management
- Training and educational capacity to build competences
- Public involvement

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

The access to information provided in self-assessment forms is granted to the public.

The relevant data fields concerning details of the nominated contact persons are published.

Data contained in non-active self-assessment forms for registration in the Enpr-EMA database are retained within EMA servers for the purpose of legal certainty for 2 years after the end of membership with Enpr-EMA.

### 4. How do we protect and safeguard your information?

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. 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.

### 5. How can you verify, modify or delete your information?

Any person whose personal data has been processed by EMA has the right to access their data at any time. In case you wish to verify which personal data is stored by the responsible data Controller, have it modified, corrected or deleted, please contact the data Controller by using the Contact information at the end of this statement and by explicitly specifying your request.

*Please see detailed information on your rights in the general EMA Privacy Statement:* <u>www.ema.europa.eu/en/about-us/legal/privacy-statement</u>

### 6. How long do we keep your data?

Your personal data will remain in the Enpr-EMA 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.

## 7. Contact information

In case you wish to verify which personal data is stored on your behalf by the responsible data Controller, have it modified, corrected, or deleted, or if you have questions regarding the Enpr-EMA network database or concerning any information processed in the context of Enpr-EMA membership, or on your rights, you are invited to contact the support team, operating under the responsibility of the data Controller using the following contact information:

enprema@ema.europa.eu

### 8. Recourse

Complaints, in case of conflict, can be addressed to:

- Data Controller: enprema@ema.europa.eu; or
- EMA Data Protection Officer: <u>dataprotection@ema.europa.eu</u>; or
- <u>European Data Protection Supervisor</u>. For more information on the complaint procedure: <u>https://edps.europa.eu/data-protection/our-role-supervisor/complaints\_en</u>