



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 December 2019  
EMA/667909/2019

## European Medicines Agency's Privacy Statement For the EMA Account Management system

The European Medicines Agency (hereinafter 'EMA' or 'Agency') is committed to respecting the right to data protection of the public. The Agency collects and uses personal data in accordance with 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 (hereinafter 'Regulation').

This Privacy Statement explains how the Agency collects and uses the most essential details of how personal data for purposes related to the EMA Account Management system. This system involves the collection and processing of the personal data of stakeholders, interested persons, delegates, staff, contactors and the general public. If you fall into one of these categories, it is important that you read and retain this statement, together with any other privacy statements EMA may provide on specific occasions when it is collecting or using personal data about you, so that you are aware of how and why EMA is using such data, and what your rights are under the Regulation.

### 1. Who is responsible for 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 Deputy Executive Director is appointed as a 'Data Controller' to ensure the lawful conduct of this processing operation.

The contact details of the Data Controller are the following: [DEDdataprotection@ema.europa.eu](mailto:DEDdataprotection@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:

- Maintain the hardware and software infrastructure required to support processing of the data in compliance with EU legislation.

The contact details of the data processor(s) are the following: IT4U Consortium,  
[IT4U.EMA@everis.com](mailto:IT4U.EMA@everis.com)

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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- Support users in accessing EMA systems by approving, enabling and unlocking user accounts.

The contact details of the data processor(s) are the following: AXIN+ Consortium, [axinplus@axians.com](mailto:axinplus@axians.com)

## 2. Purpose of this data processing

The purpose of this data processing activity is the verification of users' accounts including:

- Providing access to other systems operated by EMA, including for example:  
Eudralink, EudraCT Secure, Service Desk Portal, European union telematics controlled terms (EUTCT), EudraVigilance, EudraVigilance data analysis system (EVDAS), EudraPORTAL, European pharmacovigilance issues tracking tool (EPITT) or periodic safety update repository (PSUR repository), Substance, Product, Organisation And Referential (SPOR) portal, IRIS | Regulatory & Scientific Information Management Platform
- Communication between the users and EMA (e.g. regarding any next steps or key changes to the system or reporting problems)
- Self-service password management.

## 3. What personal data does EMA collect and how?

### 3.1. Personal Data concerned

In this processing operation we collect personal data directly from you when you submit the registration form (<https://register.ema.europa.eu/identityiq/external/registration.jsf#/register>) to open a user account in the Agency's system. Such data includes the following:

- First name and last name
- e-mail address
- Phone number (if provided)

### 3.2. Legal Basis for data processing

When you provide your data, you consent to the processing of that data in accordance with this Privacy Statement. 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.

In addition, the processing of personal data in the context of the EMA Account Management system is necessary for the performance of the Agency tasks as required by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC and other applicable Union legislation. The processing of personal data in the context of the EMA Account Management system is therefore necessary for the management and functioning of EMA and the performance of EMA's tasks in the public interest on the basis of Article 5(1)(a) of Regulation (EU) 2018/1725.

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

The data collected will be processed internally by staff within the EMA Service responsible for information security services and by contractors responsible to provide the Service Desk and system maintenance services (who are indicated above as data processors in Section 1.2).

## 5. Data Security

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

The personal data of users, are normally collected through EMA's Account Management system, which abides by the security provisions established in the Agency's security policies. Access by EMA internal users is password-protected.

## 6. 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 Privacy Statement provides information on how EMA collects and uses your personal data.
- **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 consent to the use of your personal data which are necessary (and not merely optional) for your registration, it will not be possible for you to continue to have a user account in the EMA Account Management system. As a result, EMA will close your user account. EMA will advise you first before closing the account 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 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](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).
- **Right to object** – If the Agency processes your data for the performance of a task in the public interest (without your consent or another lawful basis), you have the right to object to this processing on grounds related to your particular situation.

- **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 privacy 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)

## 7. How long does EMA keep personal data?

Your data will be deleted after 180 days of inactivity on EMA systems (i.e. if you do not use your account on any of the systems). You will receive a reminder before your data will be deleted.

## 8. 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 the **Data Controller** at [DEDdataprotection@ema.europa.eu](mailto:DEDdataprotection@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)