



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/112375/2026

## European Medicines Agency's Data Protection Notice For the EMA Account Management System

The European Medicines Agency (hereinafter "EMA" or "Agency") processes the personal data of a natural person (individual) in compliance with "Regulation 2018/1725<sup>1</sup>."

This Data Protection Notice explains the most essential details of the processing of personal data by the Agency in the context of the EMA Account Management System. This includes the collection and processing of personal data of the Agency's partners and networks<sup>2</sup>, interested persons, delegates, EMA staff and contactors. If you belong to one of these categories, it is important that you read and retain this data protection notice, together with other notices EMA provides when it is collecting or using your personal data so that you are aware why EMA is processing your personal data you understand your data protection rights.

### 1. Who is responsible for processing your data?

#### 1.1. Who is the data controller?

The Agency is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Information Security service 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.informationsecurity@ema.europa.eu](mailto:datacontroller.informationsecurity@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 to carry out the following activities:

- Maintain the hardware and software infrastructure required to support processing of data in compliance with EU legislation. The contact details of the processors are the following:
  - NTT Data Belgique SRL  
Société responsabilité limitée/Besloten Vennootschap met Beperkte Aansprakelijkheid  
Rue de Spa 8, 1000 Brussels, Belgium
  - Adinsec BV (Commercial name Grabowsky)  
Gemeenteplein 13,  
1730 Asse, Belgium

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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:
  - Axianseu Digital Solutions S.A. (two sub-contractors both based in the EEA)  
Edificio Atlantis,  
Av.Dom João II, 44C,  
Piso 5, 1990-095 Lisbon, Portugal
- Provides the licenses and the underlying software hosted by the European Medicine Agency. The contact details of the processors are the following:
  - SailPoint Technologies Netherlands B.V.  
Weteringschans 165 C  
1017 XD Amsterdam  
The Netherlands  
Section I number 5070

## 2. Purpose of this data processing

The purpose of this data processing activity is the verification of user accounts in the context of performing of the Agency's tasks, including:

- Providing access to systems operated by EMA, such as:  
Clinical Trials Information System (CTIS), Union Product Database (UPD) , Product Lifecycle Management (PLM) Portal, European Shortages Monitoring Platform (ESMP), 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.
- Communicating with users of systems operated by EMA e.g., regarding updates of system functionalities or technical issues such as system downtimes.
- Self-service password management.

### 2.1. Personal data concerned

In this processing operation we collect your personal data when you submit the registration form (<https://register.ema.europa.eu/identityiq/external/registration.jsf#/register>) to open a user account with EMA. Such data includes the following:

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

### 2.2. Legal basis of the processing

Security is an essential enabler for the protection of privacy and data protection as stated by the European Data Protection Supervisor (EDPS)<sup>1</sup>. Access management is a crucial part of the security of

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<sup>1</sup> [Information Security | European Data Protection Supervisor](#)

IT systems. It involves controlling who has access to resources within EMA and ensuring that only authorised users can access specific data, applications, and systems. In accordance with Article 33 of Regulation (EU) 2018/1725, EMA as the controller and its processors are required to implement appropriate organisational and technical measures to ensure the security of the processing of personal data.

In accordance with Article 5(1)(a) of Regulation (EU) 2018/1725, the processing of your personal data in the context of the Microsoft Entra ID is necessary for the performance of a “task carried out in the public interest or in the exercise of official authority vested in the Agency”. The tasks of the Agency are set out in Regulation (EC) 726/2004 and Directive 2001/83/EC and other applicable Union legislation<sup>2</sup>. Furthermore, the security of processing of personal data is required in accordance with Article 33 of Regulation (EU) 2018/1725 and in compliance with EMA’s Security Policy.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below. You can do so by terminating your account following the guidance provided in the [EMA Account Management guidelines](#). Please note that terminating your account will prevent you to authenticate for the access to and use of EMA’s systems.

### **2.3. Transfers of personal data outside of EU**

The SailPoint Customer Relationship Management system holds data of the EMA employees responsible for the management of the software. This refers to EMA user account information which is stored in the U.S. no further user data is processed by SailPoint directly. SailPoint Technologies is a company certified under the EU-US [Data Privacy Framework](#).

EMA Account Management relies on Entra ID for user authentication, for further information about EMA authentication services please refer to [Data Protection Notice for Authentication services and Microsoft Entra ID](#).

## **3. How long do we keep your data?**

Your account will be disabled after 180 days of inactivity on EMA systems (i.e. if you do not use your account on any of the systems) or after your contract with the EMA is terminated.

Your data will be deleted after further 180 days from the date your account has been disabled. You will receive a reminder before your data will be deleted.

Logs of roles requested and revoked are stored for 15 years to support security incidents investigations. the logs contain the user identifier, the date of when access was granted and revoked and who performed the approval.

## **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 technical support (via Service Desk) and system maintenance services (see processors in Section 1.2).

Furthermore, when you request access on behalf of a specific organisation, your first name, last name and email address are visible to the user administrator of the organisation for which you have requested to be added to the organisation’s account. The user administrator of the organisation

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<sup>2</sup> [EudraLex - Volume 1 - European Commission](#)

requires these data to validate your access request and to review and eventually revoke your access if no longer required or permitted.

## 5. 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 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](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

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 Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://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.informationsecurity@ema.europa.eu](mailto:datacontroller.informationsecurity@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)