



12 September 2024
EMA/315609/2024

European Medicines Agency's Data Protection Notice For the Referentials Management System (RMS) activities

This Data Protection Notice 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 [Referentials Management System](#) (hereinafter "RMS"). RMS supports the management of referential master data to describe the attributes of medicinal products that can be used as a reference to support EU regulatory activities and business processes.

More specifically, RMS stores and publishes master data comprising lists of terms (controlled vocabularies) to describe the attributes of medicinal products, such as lists of dosage forms, units of measurement and routes of administration made also publicly available. These master data are intended to support EU-wide regulatory activities, by enabling stakeholders in the European medicines regulatory network to uniquely identify medicinal products.

1. Who is responsible for the processing of your data?

1.1. Who is the data controller?

EMA is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Information Management Division 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.infomanagement@ema.europa.eu

1.2. Who is the data processor?

1.2.1. EMA Data Stewards

The Agency engages third parties to process data on behalf of EMA, to provide and improve the service, enable use of service features and provide customer support. This group of support is dubbed EMA Data Stewards.

The contact details of the data processor(s) are the following:

Syneos Health Netherlands B.V.
De Entrée 99-197
1101 HE Amsterdam
Netherlands



In addition, data processing in RMS is designed to use different supporting software. When you submit changes request in RMS, these changes will be handled by either:

- EMA Data Stewards via RMS portal/IDD MDM; or
- EMA Data Stewards via Service Desk/tickets in the ServiceNow portal.

1.2.2. Service Providers, Business Partners and Others

EMA works with third-party service providers to provide application development, hosting, maintenance, back-up, storage, virtual infrastructure, analysis and other services for us. These third-parties may have access to or process your Information on need-to know basis as part of providing those services for us.

2. Purpose of this data processing

The purpose of this data processing activity is to allow stakeholders to support the implementation and management of RMS, a public single source of validated referentials data that is used as a reference to support EU regulatory activities and business processes.

The management of RMS Dictionary includes:

Purpose	Actions	Parties involved
To implement RMS and manage change requests through RMS portal/IDD MDM	Handle any change request related to Add/Update/Delete RMS terms and/or Add/Update RMS Lists. Collect information to support the requested change.	EMA Data Stewards*
To provide requestor reference information in support of EU regulatory activities and business processes	Make RMS master data publicly available	EMA Data Stewards*
To provide customer support platform (through ServiceNow tool)	Answer questions, respond to request for information; Change requests to fields not included on the RMS portal change request form	EMA Data Stewards*
To implement platform improvements, troubleshoot and/or manage technical issues	Platform development and maintenance through RMS	IT support

**EMA Data Steward is responsible for ensuring high-quality data of the organisation's data.*

2.1. Personal data concerned

In this processing operation RMS/EMA processes data directly collected from you when you submit an RMS Change Request through RMS portal. Such data may include the following:

Personal Data Category	Types of Personal Data
1. User Information	<ul style="list-style-type: none"> Requestor Name/Username Contact Email Address Contact Phone Number (optional)

When you submit a Service Desk/tickets through ServiceNow portal. Such data may include the following:

Personal Data Category	Types of Personal Data
1. User Information	<ul style="list-style-type: none"> Name Email Address Browser Phone Number (Optional) Mailing Address (Optional) User Information if included in EMA's Azure Active Directory¹ Unique User ID (UUID)
2. Host and Usage Information	<ul style="list-style-type: none"> IP Address User Agent Identifier Hardware Type Operating System Type and Version Client Version IP Addresses Along the Network Path MAC Address of Your Client (As Applicable) Service Version Actions Taken Geographic Region Performance, Troubleshooting, and Diagnostics Information
3. User-Generated Information	<ul style="list-style-type: none"> Information provided by end user when creating a ticket (e.g., description, attachments)

¹ Azure Active Directory (Azure AD) is a cloud-based identity and access management service. Azure AD enables EMA employees to access external resources, such as Microsoft 365, the Azure portal, and other SaaS applications. Azure Active Directory also helps staff access internal resources like apps on EMA's corporate intranet, and any cloud apps developed for EMA.

2.2. Legal basis of the processing

The processing of personal data in RMS is necessary for the performance of the Agency's tasks carried out in the public interest as set out in Article 5(1)(a) of Regulation (EU) 2018/1725 and as required in by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC and other applicable Union legislation.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of EU

Your information may be shared with service providers located in third countries. Any such transfer complies with the provision of Chapter V of the European Union Data Protection Regulation (EU DPR) on transfers of personal data to a country outside the EEA.

3. How long do we keep your data?

The personal data processed in RMS portal and ServiceNow is retained for a period of 10 years from the date of the service being requested. This is because there is an operational requirement to retain the data for this period as they are integral part of a regulatory/core business system.

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

The following groups have access to your information:

- EMA staff involved in the processing;
- EMA Data Stewards contracted by EMA to provide the data management services;
- Very occasionally maintenance teams, auditors, operational security services employed by the EMA;

Within EMA, access rights are restricted on a need-to-know basis. For example, the Information Management Division has access to the data contained within tickets for IT requests and the facilities department has access to the data contained within tickets for requests relating to facilities.

There are administrators that have unrestricted access to the data held in ServiceNow, this access is necessary for the assignment of access rights and the overall management of ServiceNow.

In addition to this, for individual requests, specific staff can be assigned as a watcher and are therefore also able to track a request (in addition to the requestor). A watcher is assigned by the requestor, therefore the watcher is granted access to the data by the requestor.

ServiceNow and the sub-processors that they use for the general subscription service may have access to your data as is required to provide the service.

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.
- **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

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.infomanagement@ema.europa.eu or the **EMA Data Protection Officer** at 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