

15 May 2024 EMA/123948/2023 Rev. 1

European Medicines Agency's Data Protection Notice For the EMA Help Desk

The European Medicines Agency (hereinafter "EMA" or "Agency") processes the personal data of a natural person in compliance with "Regulation 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".

This Data protection notice explains the details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") when implementing the IT Service Management process, available to the public as the **EMA Help Desk**. This process enables EMA to handle the flow of IT service requests/incident tickets or other activities listed below with internal/external stakeholders.

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 I 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 are the data processors?

The Agency engages third parties to process data on behalf of EMA and in particular to provide and improve the service, enable use of service features and provide customer support. To set up this process, the EMA engaged two key resources: the supporting software (ServiceNow) and the third-party data stewards who handle 1st and 2nd line customer support (AXIANSEU).

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

ServiceNow Luchthaven

Nationaal 1K



Axianseu Digital Solutions S.A.

Edificio Atlantis, Av.Dom João II, 44C, Piso 5, 1990-095 Lisbon

2. Purpose of this data processing

The purpose of this data processing activity is to allow stakeholders to raise service requests, incidents, change requests and to support release management and problem ticket management in the context of ISO/IEC 20000 and the Information Technology Infrastructure Library (ITIL) in relation to the IT Services provided by the EMA. Stakeholders can use the service to perform troubleshooting and to allow billing of EMA usage by ServiceNow in the context of performing of the EMA tasks, including:

- · Raising Service Requests for IT Services offered by EMA
- · Raising Incident tickets for IT Services offered by EMA
- Raising Change requests tickets for IT Services offered by EMA
- Release management for IT Services offered by EMA
- Raising Internal IT service requests
- Facilitating dialogue and internal or external participant engagement in relation to the IT Services provided by EMA, including:
 - Managing questions and answers
 - Capturing input and feedback from participants on specific topics via surveys

At no point will your personal data be used for:

- Producing decisions that would result in legal or other significant effects impacting the rights of data subjects based solely by automated means
- Selling your personal data
- Serving advertisements on EMA's platform
- Tracking your usage or content for advertising purposes

2.1. Personal data concerned

In this processing operation EMA process data directly collected from you when you access and use the ServiceNow services. Such data may include the following:

Personal Data Category	Types of Personal Data
1.User Information	Name

Personal Data Category	Types of Personal Data
	Email Address
	Browser
	Phone Number (Optional)
	Mailing Address (Optional)
	User Information if included in EMA's Azure Active Directory ¹
	Unique User ID (UUID)
2.Host and Usage Information	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	Information provided by end user when creating a ticket (e.g., description, attachments)

2.2. Legal basis of the processing

The legal basis for the provision of EMA Help Desk processing activities is set in Article 5.1(a) of Regulation (EU) No 2018/1725. The establishment of an IT Help Desk is essential for the daily operations and governance of the Agency, in accordance with the requirements set forth by the EMA's Founding Regulation (EC) No 726/2004, along with additional EU laws. The IT service provided via the EMA Help Deks, coupled with the engagement with stakeholders and the general public, are crucial for executing EMA's duties carried out in the public interest.

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

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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

2.3. Transfer of personal data outside of EU

EMA has taken all reasonable contractual measures to restrict data transfers to the minimum required by the service, based on additional safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.

In particular:

- The service provided to the EMA by ServiceNow is provisioned through ServiceNow's Protected Platform for the European Union (SPP EU). SPP EU aims to minimise the amount of data transfers that are made to countries outside of the EU. SPP EU assists customers by significantly reducing the number of data transfers to outside the EU when customers are using ServiceNow products.
- By default, all data, including User-Generated Information, created by users when they use ServiceNow, is stored in ServiceNow's data centres within the EEA.
- ServiceNow has made substantial improvements to restrict data transfers outside of the EU to situations where they are critical or under the customer's control. There are limited exceptions where data transfers to outside the EU may still occur even when customers participate in SPP EU.
- The exceptions to the SPP EU contractual commitment to not transfer EU-hosted personal data out of the EU are limited to the following:
 - Where non-EU access has been approved by the customer in advance.²
 - Where required to prevent or remediate a material issue involving security, data loss, prevention, disaster recovery or critical maintenance/service availability.³
 - Where required by law or to prevent fraud or abuse.4
 - Where data is documented in a Support Portal interaction (by or on behalf of the customer), provided that ServiceNow personnel accessing such interactions are located in the EU. Note that Customers can control what data they put or request to be put in the Support Portal.

In the case of exceptions to data being processed solely outside the European Economic Area (EEA), ServiceNow has put safeguards in place such as Standard Contractual Clauses and technical and organisational measures. Information on ServiceNow's security measures can be found here, more information on the appropriate safeguards used by ServiceNow can be found <a href=here.

For more information on ServiceNow's commitment to Data Privacy see here.

 $^{^2}$ For example, a scenario where a customer grants an exception directly in relation to a particular function, such as wanting to work with particular ServiceNow personnel based outside of the EU for a specific reason.

³ Examples of where this exception may apply include but are not limited to: EU support center is down and cannot correspond with Customers; EU datacenter is down, and extra staff is needed to support incoming cases; national network outage; ServiceNow network component is down for the EU.

⁴ It may be possible that ServiceNow could be involved in litigation with a Customer or related party that mandates certain data disclosures, or ServiceNow could also become aware of fraud / payment avoidance / systems manipulation / targeted attacks / other illegal activity, in which case ServiceNow would need to reserve the right to have any necessary access to Customer data to prevent or remediate such issues.

3. How long do we keep your data?

In accordance with operational protocols, personal data collected through ServiceNow will be maintained for a period not exceeding five years following the initial service request. This retention period is necessitated by operational needs to ensure the data remains available for the duration required.

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

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 in a request by the requestor.

ServiceNow and the sub-processors may have access to your data as is required to provide the service. For a full list of the general subscription sub-processors please see here.

5. Your data protection rights

As data subject (i.e., the individual whose personal data is processed), you have several 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 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 your consent, EMA may not be able to provide certain services to you. EMA will advise you 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 EMA 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. 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 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.

 Right not to be subject to automated decision making – You have the right to not to be subject to a decision based solely on automated processing if such decision has legal effect on you.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. Please note that there are limitations and exceptions to these rights, more information on this can be found here. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA Data Protection and 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

<u>Datacontroller.infomanagement@ema.europa.eu</u> or the **EMA Data Protection Officer** at<u>dataprotection@ema.europa.eu</u>.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

Email: <u>edps@edps.europa.eu</u>

Website: <u>www.edps.europa.eu</u>

Further contact information: <u>www.edps.europa.eu/about-edps/contact_en</u>