



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 January 2025
EMA/593972/2024

Records of data processing activity (public)

For the Organisation Management System (OMS) activities

1.	Last update of this record, version number:	24 January 2025
2.	Reference number:	EMA/593972/2024
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Information Management Division Contact: Datacontroller.infomanagement@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	Syneos Health Netherlands B.V. De Entrée 99-197 1101 HE Amsterdam Netherlands
7.	Purpose of the processing	The purpose of this data processing activity is to allow stakeholders to support the implementation and management of OMS, a public single source of validated organisation and location data that is used as a reference to support EU regulatory activities and business processes. The management of OMS Dictionary includes: Purposes: • Implement OMS and manage change requests through the OMS portal ○ Actions: Collect and update organization/location information ○ Parties involved: EMA Data Stewards*



		• Provide organization reference information in support of EU regulatory activities and business processes ○ Actions: Make organization/location information publicly available ○ Parties involved: EMA Data Stewards* • Offer a customer support platform (via ServiceDesk) ○ Actions: Answer questions, respond to requests for information, and handle change requests for fields not included in the OMS portal form ○ Parties involved: EMA Data Stewards* • Implement platform improvements, troubleshoot, and manage technical issues ○ Actions: Develop and maintain the platform through OMS ○ Parties involved: IT support • To verify the proof of identity of sole traders, entrepreneurs/ individuals who are not publicly registered and who are actively participating in one of the following regulatory procedures: as a Marketing Authorization Holder (MAH) in EudraVigilance (EV), in any role within the EudraDMDP, or as a MAH in the Union Product Database (UPD) ○ Actions: Collect the individual's identity document ○ Parties involved: Designated EMA staff
8.	Description of categories of persons whose data EMA processes and list of data categories	In this processing operation, OMS/EMA processes data directly collected from the organisation when they submit an OMS Change Request through the OMS portal. Such data may include the following: Personal Data Category: ○ User Information • Types of Personal Data: ○ Requester Name ○ Email Address ○ Phone Number (optional) When Service Desk request/tickets is submitted through EMA's portal. Such data may include the following: Personal Data Categories: 1. User Information • Types of Personal Data: ○ Name ○ Email Address ○ Browser ○ Phone Number (Optional) ○ Mailing Address (Optional) ○ User Information if included in EMA's Azure Active Directory ○ Unique User ID (UUID)

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

		2.Host and Usage Information - Types of Personal Data: - IP Address - User Agent Identifier - Hardware Type - Operating System Type and Version - Client Version - IP Addresses Along the Network Path - MAC Address of Client (as Applicable) - Service Version - Actions Taken - Geographic Region - Performance, Troubleshooting, and Diagnostics Information 3.User-Generated Information - Types of Personal Data: - Information provided by end user when creating a ticket (e.g., description, attachments)
9.	Time limit for keeping the data	The personal data processed in OMS portal and EMA's Service Desk 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. If a natural person securely provides proof of identity, once that individual's identity is successfully verified, the copy of the ID document will be permanently deleted. This measure ensures that personal data is not retained beyond necessity and minimises the risk of unauthorized access.
10.	Recipients of the data	The following groups have access to individual's 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; - Public (organisation name, organisation address, optional e-mail address and telephone number which the individual provide based on consent). 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 EMA's Service Desk, this access is necessary for

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

		the assignment of access rights and the overall management of ServiceDesk. 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 requester; therefore, the watcher is granted access to the data by the requester. The vendor of EMA's Service Desk and their sub-processors for the general subscription service may have access to personal data as is required to provide the service.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Information may be occasionally shared with service providers located in third countries. Such transfer complies with the provision of Chapter V of the European Union Data Protection Regulation (EUDPR) on transfers of personal data to a country outside the EEA i.e. Article 50(1)(d) of Regulation (EUDPR) 2018/1725. When personal data is made available in the public domain of OMS and accessed from outside the EU/EEA, it is done in accordance with Article 50(1)(g) of Regulation (EU) 2018/1725. This regulation permits the transfer of data from a register intended by Union law to provide information to the public, which is open for consultation by the general public or by individuals demonstrating a legitimate interest. Such access is allowed only when the specific conditions for consultation outlined in Union law are met in each particular case. This approach acknowledges that the publicly available information in OMS is essential for supporting the regulatory processes of the European Medicines Regulatory Network, as specified in pharmaceutical legislation. The information is necessary for the operation of key databases, including the database on medicinal products as established in Article 57(l) of Regulation (EU) 726/2004 and the Union product database for veterinary medicinal products as outlined in Article 55 of Regulation (EU) 2019/6, both of which must be accessible to the public.
12.	General description of security measures, where possible.	To protect personal data of data subjects, EMA has in place several contractual safeguards complemented by technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data, not publicly available, solely to authorised

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

		persons with a legitimate need to know for the purposes of this processing operation. Information on Syneos Health Netherlands B.V.'s security measures can be found here.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement Here you may find the data protection notice regarding this specific data processing operation as well. EMA-I-010-DPN-Organisation Management System (OMS) EMA/565742/2023 https://docs.eudra.org/webtop/drl/objectId/090142b285fd5c5a