

EMA/184133/2025 29 August 2025

European Medicines Agency's Data Protection Notice

For the EU NTC Learning Management System

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 EU NTC Learning Management System (LMS).

1. Who is responsible for processing 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 Head of Digital Business Transformation Task Force 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: datacontrollertdt@ema.europa.eu

1.2. Who is the data processor?

The Agency engages a third party to process data on behalf of the Agency to store learning progress and history associated with user profiles.

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

Platform	Data processor	Contact
EMA Talent Hub	SAP Amerikastraat 10 5232 BE 's-Hertogenbosch Phone: +31 (0)73 645 75 00	privacy@sap.com



Fax: +31 (0)73 645 7300

2. Purpose of this data processing

The purpose of this data processing activity is to manage personal data in the context of performing the Agency's tasks related to the EU Network Training Centre. These tasks generally involve streamlining educational processes for external users, such as from national Competent Authorities (NCAs) in the European Economic Area (EEA). Specifically:

- Creation and distribution of audiovisual material intended for course content.
- Collecting personal data of NCA staff members for the purpose of registration of course participants.
- Storing data of course participants including course progress and completion status for monitoring purposes and for offering synchronous trainings.
- Managing user accounts for the purpose of creating, updating, and deleting profiles.
- Communicating with users for the purpose of sending notifications, updates, and feedback.
- Generating reports on user performance, course completion rates, and other analytics (statistical analysis).
- Technical information for auditing and security purposes.

2.1. Personal data concerned

In this processing operation we process data directly collected from you when you register to the LMS as well as other data gathered through your use of the platform, completion of courses and occasional participation in recorded live sessions. Such data may include the following:

Category of data subjects concerned	Personal data processed
Course creators and instructors	 Email address Technical data stored by the processor (e.g., IP or user agent, log files) Depending on the form of the deliverable, this may also include: Video and audio recording Full name

Category of data subjects concerned	Personal data processed
Individuals attending courses* that will be uploaded to the LMS (e.g., live interactive sessions)	Video and audio recordingFull nameEmail address
Users of the LMS	 Full name Email address Country and region of employment Authority or agency, job role, and area of interest. Learning history: courses enrolled, status of completion, grades obtained, dates of registration and completion Technical data stored by the processor (e.g., IP or user agent, log files)

^{*} The Agency will inform the participants of live interactive sessions that the course will be recorded and updated to the LMS, and their personal data processed in accordance with this Data Protection Notice. Should the participants wish not to appear in the recording, they will be advised not to turn on their microphones and cameras, and refrain from making comments in the chat.

2.2. Legal basis of the processing

The processing of your personal data is based on the following legal basis:

Category of data subjects concerned	Legal basis of the processing of your personal data
Course creators and instructors	The processing of personal data in the creation and
	distribution of course materials 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 (EUDPR) and as required in by
	Regulation (EC) No 726/2004, Directives 2001/83/EC
	and 2001/82/EC and other applicable Union legislation.
Individuals attending courses* that will	When you provide your data when participating in a live
be uploaded to the LMS (e.g., live	interactive session that will be uploaded to the LMS, you
interactive sessions)	consent to the processing of that data in accordance with
	this Data Protection Notice, and in line with Article
	5(1)(d) of Regulation (EU) 2018/1725. You may opt-out
	from the processing in a response to the contact person
	mentioned in Section 1.1, or directly through the

Category of data subjects concerned	Legal basis of the processing of your personal data
	Learning Management System. In your response, please state what is the personal data that you want to exclude and what is the actual processing activity that you do not want EMA to carry out on your data. 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.
Users of the LMS platform	When you provide your data when registering to the LMS you consent to the processing of that data in accordance with this Data Protection Notice, and in line with Article 5(1)(d) of Regulation (EU) 2018/1725. You may opt-out from the processing in a response to the contact person mentioned in Section 1.1, or directly through the Learning Management System. In your response, please state what is the personal data that you want to exclude and what is the actual processing activity that you do not want EMA to carry out on your data. 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.

2.3. Transfer of personal data outside of EU

Access might be granted to specific authorised users from outside the EU in the context of collaboration with the Instrument for Pre-Accession Assistance (IPA) countries¹ and the African Medicines Agency (AMA) countries², meaning that they will have access to the email of the course lead and, potentially, faces, voices or usernames of participants from a live session. The number of courses available to these users is very limited and, as any other user, they need to be registered and identified. Tools and processes will be implemented to limit the amount of personal data shared in live sessions. This exceptional transfer of personal data is based in Article 50(1)(d) of the EUDPR, i.e., the transfer is necessary for important reasons of public interest (Article 50(1)(d) Regulation (EU) 2018/1725).

In certain situations, user data may need to be shared with third parties outside the European Union (EU) for the purpose of providing support related to specific issues or technical assistance. This

¹ The IPA III was established in Regulation (EU) 2021/1529 of the European Parliament and of the Council of 15 September 2021 establishing the Instrument for Pre-Accession assistance (IPA III), accessible here: https://eur-lex.europa.eu/leqal-content/EN/TXT/PDF/?uri=CELEX:32021R1529&from=EN
² Treaty for the Establishment of the African Medicines Agency, adopted on 11 February 2019, accessible here:

https://au.int/sites/default/files/treaties/36892-treaty-0069 - ama treaty e.pdf

transfer will only occur after obtaining prior approval from the user. In general, this approval will be required before sharing any data with the third party. However, in cases of very high urgency, such approval may be granted without delay, but only under exceptional circumstances. We ensure that any such transfers are done in compliance with applicable data protection laws, and appropriate safeguards are in place to protect your personal data.

3. How long do we keep your data?

Your data will be stored for as long as you, as user, remain active in the platform.

Any records produced will remain stored for three years after your account is deactivated and will be deleted automatically thereafter.

Personal data included in the course material will be retained only for as long as it is required to fulfil the educational purpose for which it was collected, after which it will be securely deleted.

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

The data collected will be processed internally by authorised EMA staff within the EMA Digital Business Transformation Taskforce, namely the EU NTC core team.

Training records can only be accessed by system administrators of the LMS. Where necessary, records might be accessed by EMA's processor for maintenance and/or technical support.

Technical data (such as IP or user agent) associated with your user ID might be accessed by the processor only if requested by EMA in the course of an investigation of a potential security incident.

For organisational purposes, specific records of attendees (name, email, and affiliation) will be shared with course organisers in the context of specific webinars or other courses.

Local administrators of medicines regulatory authorities can access the records of course registration and completion of their respective users.

Users will have access to the course creator/instructor's email address, as well as any other personal data that might appear in the course content including images, voices or usernames in recordings of live sessions.

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 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, the Agency 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 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 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.
- 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 datacontrollertdt@ema.europa.eu or the **EMA Data Protection Officer** at:

• Email: <u>dataprotection@ema.europa.eu</u>

• Postal address: European Medicines Agency

PO Box 71010

1008 BA Amsterdam

The Netherlands

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

• Further contact information: www.edps.europa.eu/about-edps/contact_en

7. Annex I

Logging into the EU NTC LMS:

By logging into the EU NTC LMS:

• I give consent to the European Medicines Agency to process my personal data in accordance with the Data Protection Notice for EU NTC LMS.

IMPORTANT: The Data Protection Notice (link) provides necessary details, and we urge you to read it carefully prior to logging into the EMA Talent Hub and providing your personal data.

By giving consent to provide personal data in accordance with the Data Protection Notice, you will have access the EU NTC learning catalogue. This offer aims at helping you to perform well in your current role, as well as further develop your career.

You 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.

datacontrollertdt@ema.europa.eu