



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 July 2024
EMA/79065/2024

European Medicines Agency's Data Protection Notice

Regulatory Science and Innovation Task Force (TRS) activities

This Data Protection Notice explains the most essential details of the processing of personal data carried out by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of its horizon scanning and forecast activities, identification of regulatory science needs, and interactions with Academia.

EMA is committed to respect the right to data protection of its staff members and the public. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 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.

In order to comply with the Agency's mission to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health it is important for the Agency to be aware of the latest scientific knowledge and methodologies and to actively support science in relevant areas.

Who is responsible for 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 the Regulatory Science and Innovation Task Force (TRS) is appointed as an 'Internal Controller' to ensure the implementation of the processing of personal data.

The contact details of the Internal Controller are the following:
datacontroller.horizonscanning@ema.europa.eu

1. Purpose of this data processing

The purpose of this data processing activity is to handle personal data exchanged with TRS in the context of its horizon scanning and forecast activities, identification of regulatory science needs, and relevant interactions with companies, public bodies, consortia, research centres, academia, and natural persons. These interactions aim at collecting relevant information for the Agency to prepare horizon

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scanning reports, forecast future submissions via the centralised procedure, plan workload and expertise needed within the regulatory network, and identify regulatory science needs.

This Data Protection Notice applies to the below-mentioned processing activities:

- Business pipeline e-update
- Early Point of Contact (EPOC) tracking table
- Tracking table for academia interactions Tracking table for European projects
- Portfolio and Technology meeting (PTM)
- Innovation task force (ITF) meeting

These activities are further highlighted in the Agency website under the *Innovation in medicines* section ([link](#)).

1.1. Personal Data concerned

Personal data refer to any information relating to an identified or identifiable natural person (“data subject”). An identifiable natural person is one who can be identified, directly or indirectly, in particular by an identifier such as name, an identification number or others¹.

When submitting an application as part of one of the regulatory procedures described above, personal data of any person creating, editing, submitting an application to interact with EMA may be included. Please see the tabular overview of the data processing activities in section 2.3 for a detailed overview of personal data categories concerned in each activity.

These personal data will be kept in the application form of the different interactions ([link](#)), internal records, and internal databases.

1.2. Legal Basis

The processing of personal data for the purpose stated above are necessary for the performance of the Agency’s tasks carried out in the public interest as set out in Union pharmaceutical and medical device legislation governing the scientific and regulatory procedures.² Therefore, data processing is based on Article 5(1)(a) of the EUDPR, i.e., the processing is necessary for the performance of EMA’s task in the public interest.

In cases where the processing is not necessary for performing a task in the public interest, data processing is based on consent according to Article 5(1)(d) of the EUDPR. When consent is used as a legal basis for the processing of personal data, the data controller ensures the consent is freely given, informed, specific, and unambiguous, meaning that individuals have a free choice regarding whether or not they agree with the processing of their personal data; they have sufficient information to understand which data is processed, for what purpose, and how this is done. In addition, data subjects can withdraw their consent, as explained in Section 5 below.

Please note that you have the **right to object** against the processing as explained in Section 5 below.

¹ Definition in accordance with Article 3(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 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)

² [EudraLex - Volume 1 - European Commission \(europa.eu\)](#)

1.3. *Tabular view of data processing activities*

Processing activity	Personal data concerned	Data subject concerned	Legal basis	Retention period
Business pipeline e-update	Email address; EudraLink credentials	Point of contact within the pharmaceutical company	Public interest	25 years
Early point of contact (EPOC) tracking table	Name; email address; business telephone number	Point of contact within the entity requesting the interaction	Public interest	25 years
Tracking table for academia interactions	Email address	Point of contact in entity requesting interaction	Public interest	25 years
Tracking table for European projects	Name	EMA contact person	Public interest	25 years
Portfolio and Technology Meeting (PTM)	Email address; name; function; business telephone number	Participants to the meeting	Consent	25 years
Innovation Task Force (ITF) briefing meeting	Email address; name; function; business telephone number	Participants to the meeting	Consent	25 years

2. How long do we keep your data?

The retention period of the data is 25 years. This retention period is necessary to allow for the review of previous information regarding relevant interactions with the applicants and their potential marketing authorisation applications in line with the mission of the Agency.

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

The data collected will be processed internally by authorised EMA staff within TRS and the Agency staff have a read access on a need-to-know basis.

4. 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.
- **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 data if it is incorrect or incomplete.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing of your personal data, 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 Data Protection and Privacy, hosted at <https://www.ema.europa.eu/en/about-us/data-protection-privacy>.
- **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.
- **Right to withdraw consent** – When consent is the legal basis for personal data processing, you have the right to withdraw your consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

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 Data Protection and Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

5. 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 **Data Controller** at the address reported in section 1.1 above, 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