02 October 2025
EMA/321117/2015

European Medicines Agency's Data Protection Notice

For the TRIP Digital workstation for Horizon scanning and Regulatory science

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 collecting, curating, and assessing public information on important developments for the purpose of Horizon scanning and Regulatory science research.

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 the Regulatory Science and Innovation 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: datacontroller.horizonscanning@ema.europa.eu.

1.2. Who is the data processor?

The Agency engages a third party to process data on behalf of the Agency, in particular, to host the TRIP Digital workstation. The contact details of the processor are the following:

Microsoft Ireland Operations Limited

One Microsoft Place, South County Business Park,

Leopardstown, Dublin 18 D18 P521, Ireland

Telephone: +353 (1) 706-3117

If you have a privacy concern, complaint, or question for the Microsoft Chief Privacy Officer or the Data Protection Officer, please contact them by using this web form.

2. Purpose of this data processing

The purpose of this data processing activity is the collection, curation, and assessment of public information on important developments in terms of science, medicine or regulation in the context of performing of the Agency tasks, including:

- Providing latest scientific insights on topics that are, or might become, relevant to EMA's regulatory framework, and to collaborate on the collection and annotation of that information;
- Implementing horizon scanning capabilities required in the European Medicines Agencies Network (EMAN) strategy.

2.1. Personal data concerned

In this processing operation the Agency may process:

- Limited user personal data (i.e., name, surname, email address) for authentication and flagging last edits of an item. TRIP neither tracks user activities nor records any sequence of users curating or editing items.
- Limited personal data from publicly available publications (e.g., name, surname, affiliation, email address of the corresponding authors of the publications).

2.2. Legal basis of the processing

The personal data processing in TRIP is necessary for the performance of the Agency tasks carried out in the public interest as required by Regulation (EC) No 726/2004[1], Regulation (EU) 2021/2282[2] and other applicable Union legislation.

In particular, the processing of data is necessary for the performance of tasks carried out in the public interest, as required by Articles 56(1)(f) and 57(1) of Regulation (EC) No 726/2004; in recitals 42 and 46, and for activities in Articles 6(3)(b) and 22(2)(b) of Regulation (EU) 2021/2282. This is in order to provide the best possible scientific advice on any question relating to the evaluation of the quality, safety, and efficacy of medicinal products. 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

As part of the tools enabling TRIP users to carry out their tasks as set out in section 2, the Agency's processor (see section 1.2) and their sub-processor(s)[3] may transfer certain data to third countries. As part of the transfer of such personal data, the Agency's processor is relying on the following transfer mechanisms:

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
[2] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.
[3] A list can be provided upon request.

- Adequacy decision of the European Commission[4] determining whether a country outside the EU offers an adequate level of data protection, and;
- Standard Contractual Clauses of the European Commission[5] , for the countries where no adequacy decision is in place.

3. How long do we keep your data?

TRIP ingests information items that might contain a limited amount of personal data (mostly scientific publications), and users curate them as "not relevant" (such items are retained for one year to avoid duplicate ingestion and to be able to correct an erroneous curation) or as "relevant" (such items will be stored for up to 25 years for subsequent in-depth analyses unless the items are subsequently curated as "not relevant"). Only a small minority of items (up to 20%) are anticipated to be "relevant".

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

The TRIP user interface is accessible to EMA staff who have authenticated in the EMA's single-sign-on authentication mechanism[6], and for a number of EU Medicines regulatory network users. TRIP's backend data base is accessible only to selected EMA users (IT administrators and Product Owner).

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

[4] https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en
[5] https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en
[6] For more information, please see the European Medicines Agency's Data Protection Notice For the use of EMA Authentication Services and Microsoft Entra ID, accessible here: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-use-ema-authentication-services-microsoft-entra-id_en.pdf

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:

Internal Controller at datacontroller.horizonscanning@ema.europa.eu.

EMA Data Protection Officer at dataprotection@ema.europa.eu.

Address	Postal Address	EMA Switch Board
European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands	European Medicines Agency PO Box 71010 1008 BA Amsterdam The Netherlands	+31 (0)88 781 6000

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