



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 September 2021
EMA/88784/2021
Stakeholders and Communication Division

European Medicines Agency's Privacy Statement For the clinical data publication website

This privacy statement 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 user registration, access and activity on the clinical data publication website.

The clinical data publication website was developed by EMA to implement the Agency's policy on the publication of clinical data for medicinal products for human use, Policy 0070. The statement explains the reason for the processing, the way of collecting, handling and ensuring protection of all personal data provided, how that information is used and what rights you may exercise in relation to your data and how.

1. Who is responsible for processing your data?

1.1. Who is the data controller?

EMA is ultimately responsible for complying with your data protection rights and freedoms. On behalf of EMA, the Head of the Stakeholders and Communication Division is appointed as the 'internal controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:

S-DataController@ema.europa.eu

1.2. Who is the data processor?

EMA engages a third party to host, manage and maintain the database necessary for the functioning of the clinical data publication website, the Oracle Internet Directory run by Oracle Corporation. Oracle has access to the personal data.

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

Oracle Belgium BVBA
Medialaan 50, Vilvoorde
B-1800 Belgium

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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2. Purpose of this data processing

The clinical data publication website was developed by EMA to implement Agency's policy on the publication of clinical data for medicinal products for human use, Policy 0070. Access to published data is controlled to help prevent the unauthorised use of published clinical data.

Your personal data is collected and processed for two reasons:

- To authenticate you as an authorised user and therefore to grant you access to the clinical data published through your personal account;
- To record your user access and activity on the clinical data publication website.

Prior to access being granted to published clinical data, prospective users first register for an EMA account. This account provides access to various systems and platforms operated by EMA. For more information on how the Agency processes personal data provided by users of EMA accounts please read the following [privacy statement](#).

As a second step in the registration, users holding an EMA account need to accept the [terms of use](#) of the clinical data publication website.

There are access categories in line with the terms of use to the published clinical data:

- Users accessing the published clinical data for general information and other non-commercial purposes, including non-commercial research purposes. These users do not need to provide any additional personal data.
- Users accessing the published clinical data for academic and other non-commercial research purposes. This type of user allows more access rights, which requires some additional personal data. These are provided via the clinical data publication website following the acceptance of the terms of use. The additional personal data are stored in the Oracle Internet Directory.

2.1. Personal data concerned

In this processing operation we process data directly collected from you when you accept the terms of use and request access to the published clinical data for academic and other non-commercial research purposes. Such data may include the following:

- An e-mail address;
- An address in the European Union;
- Elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for legal persons, the affiliation and position within the organisation of the user should also be provided).

These personal data are not collected from users accessing the published clinical data for general information.

Other data collected regarding your user access and activity on the clinical data publication website include:

- Log in to access the clinical data published;
- Terms of use acceptance on first time log in for access;

- Terms of use confirmation to view and /or download each clinical data package or package together with a log of the documents selected for view or download;
- Terms of use acceptance on upgrade from general information purposes to academic/non-commercial research purposes;
- Saved searches for the duration that the specific search is saved;
- Profile edit/update of details stored: EMA account;
- Profile upgrade: clinical data publication access from general information purposes for academic/non-commercial research purposes.

2.2. Legal basis of the processing

When you provide your data, you consent to the processing of that data in accordance with this privacy statement. You have the right to withdraw your consent later at any time by sending a request to the internal controller (s-datacontroller@ema.europa.eu) stating that you want your access to the clinical data publication website to be closed. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent. More information about the retention period is included in point 3.

In addition, the processing of personal data by the EMA for the user access and activity on the clinical data publication website is necessary for the performance of the Agency tasks carried out in the public interest as required by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC 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 provided for under:

- Article 80 of Regulation (EC) No 726/2004 and EMA's policy on publication of clinical data for medicinal products for human use, Policy 0070.

3. How long do we keep your data?

Personal data is retained for the duration that an individual holds an EMA account and /or access to the clinical data publication website.

- General information purposes access holder who actively closes or does not use his/her EMA account (s) and /or clinical data publication website access,
 - the EMA account(s) is deemed inactive after 6 months; access to the clinical data publication website will be closed and
 - the access holder's personal details/activity will be deleted after a further 6 months.
- Academic/Non-commercial research purposes access holder who actively closes or does not use his/her EMA account and/or clinical data publication website access,
 - the EMA account is deemed inactive after 6 months, access to the clinical data publication website will be closed and
 - personal details are deleted after a further 5 years.

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

Access to your data is provided to authorised EMA staff, according to the 'need to know' principle only. Such staff abide by statutory, and when required, additional confidentiality agreements.

EMA engages a third party (data processor) to host, manage and maintain the database necessary for the functioning of the clinical data publication website, the Oracle Internet Directory run by Oracle Corporation. The data processor must ensure that personnel authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality in accordance to the contract signed with the data controller. The data processor has adopted appropriate technical and organisational security measures to prevent unauthorised access to personal data.

In accordance with the terms of use, EMA can be required to disclose your personal information by law, such as to comply with a judicial proceeding, court order, or legal process.

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 Privacy Statement 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 object** – You have the right to object at any time to this processing on grounds related to your particular situation.
- **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.

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 privacy 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 Privacy Statement or the general EMA Privacy Statement, please contact the **internal controller** at s-datacontroller@ema.europa.eu 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