EMA/228281/2024
1 December 2025

European Medicines Agency's Data Protection Notice

For the EudraVigilance Signal and Safety Analytics (EV SSA) platform

Data Protection Notice content

Executive

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 An agency of the European Union

Executive Summary

The European Medicines Agency (hereinafter "EMA" or "Agency") in collaboration with Union Member States and the European Commission (hereinafter "joint controllers"[1]), has set up and maintains the EudraVigilance[2] database and data processing network[2] (hereinafter "EudraVigilance").
The purpose is to collate and analyse information on suspected adverse reactions regarding investigational medicinal products (IMPs) studied in clinical trials and medicinal products authorised in the European Economic Area (EEA). This is to allow national Competent Authorities (NCAs), the Agency and the European Commission to access and share that information simultaneously. The processing of personal data is explained in the Data Protection Notice for EudraVigilance[3].

This Data Protection Notice explains how the joint controllers process personal data in the context of the new EudraVigilance Signal and Safety Analytics (EV SSA) platform, which serves as a supplement to the EudraVigilance Data Analysis System (EVDAS) and constitutes an integral part of the data-driven scientific assessment process for Individual Case Safety Reports (ICSRs) submitted to EudraVigilance.

In the context of the EV SSA platform, the joint controllers process personal data as required by applicable pharmaceutical and other Union legislation for:

- The establishment, operation and maintenance of the EV SSA platform
- User registration, access management and logging of user actions within the EV SSA platform
- The continuous monitoring of suspected adverse reactions reported to EudraVigilance and the assessment of the safety of medicines
- The provision of technical support.

As data subject (i.e. the individual whose personal data is processed), you have the following rights:

- Right to be informed about the processing of your personal data
- Right to access your personal data
- Right to rectification of your personal data
- Right to erasure of your personal data
- Right to restrict processing of your personal data
- Right to object to the processing of your personal data
- Right not to be subject to automated decision making

You may exercise your rights in accordance with the provisions of Regulation (EU) 2018/1725 and Regulation (EU) 2016/679 in respect of, and against each of, the joint controllers as further explained in this Data Protection Notice.

[1] EudraVigilance Joint Controllership Arrangement
[2] EudraVigilance
[3] EudraVigilance Data Protection Notice

1. Who is responsible for processing your data?

1.1. Who are the data controllers?

EMA, the European Commission (EC) and National Competent Authorities (NCAs) in Member States of the European Economic Area (EEA) are joint controllers of the EudraVigilance Human (EV) system as set out in the Joint Controllership Arrangement (JCA).

The Parties of the Joint Controllership Arrangement also act as joint controllers for processing operations in the EV SSA platform for the purpose of safety monitoring and safety assessment of medicines.

The contact points of the joint controllers are the following:

- European Medicines Agency: Head of the Division for Human Medicines Datacontroller.HumanMedicines@ema.europa.eu
- European Commission: sante-consult-b5@ec.europa.eu
- Member States: Annex I of the EudraVigilance Joint Controllership Arrangement

The respective roles and relationship vis-à-vis you and your personal data being processed, are explained in the EV JCA. In accordance with the applicable rules of the European Union Data Protection Regulation (EUDPR)[4] and the General Data Protection Regulation (GDPR)[5], you may exercise your rights (see also Section 5) under the Regulations in respect of, and against each of, the joint controllers. To ensure that any request can be handled as swiftly as possible, it is recommended that you contact the joint controller who, in line with the activities allocated in the JCA, collects, and mainly processes the personal data concerning you.

Please note that marketing authorisation holders and sponsors of clinical trials of ICSRs held in the EV SSA platform are separate controllers for their personal data processing activities carried out pursuant to the applicable pharmacovigilance and clinical trials legislation.

1.2. Who is the data processor?

The Agency has engaged a third party to carry out the following activities on behalf of the joint controllers to provide:

- The EV SSA platform supplementing the EudraVigilance Data Analysis System (EVDAS) providing the necessary functionalities for the European Medicines Regulatory Network to perform signal management activities in pharmacovigilance and safety monitoring in clinical trials.
- Technical and end user support to keep the services up to date.

The contact details of the vendor acting as data processor are the following:

RxLogix Corporation: 20801 Biscayne Boulevard, Suite 302, Aventura, Florida 33180, USA

As regards the processing operations carried out by the processor, you may exercise your rights with EMA in accordance with the EUDPR.

[4] 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.

[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

2. Purpose of this data processing

The purpose of this data processing activity is to facilitate the safety monitoring of medicinal products in the pre- and post-authorisation phases including:

- The establishment, operation and maintenance of the EV SSA platform in compliance with Article 24(1) of Regulation (EC) No 726/2004[6] and Article 40(1) of Regulation (EU) No 536/2014[7].
- The monitoring and assessment of suspected adverse reactions reported to EudraVigilance through the submission of Individual Case Safety Reports (ICSRs) to determine whether there are new risks or whether risks have changed and whether those risks have an impact on the risk-benefit balance of medicinal products. This includes the conduct of searches and generation of reports for the purpose of safety monitoring and signal detection, signal validation and signal assessment.
- User registration and access management for controlled access to the EV SSA platform for authorised users of EMA, the EC and NCAs in Member States of the EEA.
- Logging of actions undertaken by users within the EV SSA platform from the initial login to all subsequent interactions.
- Providing end user and technical support to authorised EV SSA platform users in case of troubleshooting.

The content of ICSRs is defined in the pharmacovigilance[8] and clinical trials legislation[9] as well as the good pharmacovigilance practice guidance (GVP) Module VI[10].

2.1. Personal data concerned

In this processing operation EMA processes the following personal data[11]:

Personal Data Category	Description
Category 1	• Personal data and data concerning health[12] of ICSRs reported to EudraVigilance by NCAs in Member States, marketing authorisation holders (MAHs) and sponsors of clinical trials. These data are pseudonymised[13] for ICSRs held in EudraVigilance i.e., the personal data can no longer be attributed to a specific individual without additional information which is kept separately by the reporting entities.

[6] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
[7] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
[8] Article 28 of the Commission Implementing Regulation (EU) 520/2012 and Regulation No (EU) 536/2014
[9] Annex III of Regulation (EU) No 536/2014
[10] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[11] Personal data means 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 reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (Article 3(1) EUDPR and Article 4(1) GDPR).
[12] Data concerning health means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status (Article 3(19) EUDPR and Article 4(15) GDPR)
[13] Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person ((Article 3(6) EUDPR and Article 4(5) GDPR)

Personal Data Category	Description
	The pseudonymisation of personal data is described in Module VI Addendum II – Masking of Personal Data in Individual Case Safety Reports Submitted to EudraVigilance[14]. • The name of the safety assessor (signal validator) of EMA, NCAs or independent expert appointed by the EC and the outcome of their assessments performed.
Category 2	• For user authentication, personal data from EMA's Account Management system are processed including: – First and last name and email address of the authorised EV SSA platform user. – Session cookies to keep track of the identity of the EV SSA platform user. These cookies only store what is needed to keep users authenticated while using the system. • For logging and audit purposes, the sequence of actions undertaken by an EV SSA platform user are logged. This includes the initial login and all subsequent platform interactions. This includes the following information: – IP address – Operating System – Browser – Timestamp (UTC) – All user generated events by users such as records created, deleted, exported, login success and fail attempts.
Category 3	• For support service requests: – First and last name and email address of the authorised EV SSA platform user and/or EMA technical support staff. – Optional: business phone, mobile phone, photo, title, language, time zone, date format, Department and Service, Office / location, manager, contract type (staff or contractor).

2.2. Legal basis of the processing

The Agency processes your personal data only when there is a valid legal basis to do so, in accordance with the EUDPR. In particular, the processing of:

[14] Module VI Addendum II – Masking of Personal Data in Individual Case Safety Reports Submitted to EudraVigilance

- Category 1 data for the purpose of safety monitoring is based on Article 5(1)(b) of the EUDPR as the processing is necessary for compliance with a legal obligation to which the joint controllers are subject. Such obligations stem from:
  - Article 24(1) of Regulation (EC) No 726/2004[15], requiring the Agency, in collaboration with Union Member States and the EC, to set up and maintain the EudraVigilance database and data processing network (EudraVigilance) to collate and analyse pharmacovigilance information regarding medicinal products authorised in the Union and to allow NCAs to access and share that information simultaneously.
  - Article 40 of Regulation (EC) No 536/2014, requiring the Agency to set up and maintain an electronic database (referred to as EVCTM) for the reporting of suspected unexpected serious adverse reactions (SUSARs) by the sponsor to the Agency. This database is a module of the 'Eudravigilance database' and is the central point for suspected unexpected serious adverse reaction (SUSAR) reporting for all clinical trials in the Union.
  - Chapter III of Commission Implementing Regulation (EU) 520/2012[16], establishing the minimum requirements for the monitoring of data in EudraVigilance. GVP Module IX[17] further details the signal management process and the roles and responsibilities of all stakeholders involved.
  - Article 5(1) of Commission Implementing Regulation (EU) 2022/20[18], requiring that the safety assessing Member State shall amongst other duties screen and assess information about all suspected unexpected serious adverse reactions reported in the EudraVigilance database in accordance with Article 42 of Regulation (EU) No 536/2014, regardless of whether they occurred in Member States or in third countries, as well as information contained in annual safety reports, in accordance with Articles 6 and 7 following a risk based approach.

  The corresponding appropriate condition for lawful processing of data concerning health in the context of these obligations is Article 10(2)(i) of the EUDPR i.e., the processing is necessary for reasons of public interest in the area of public health to ensure high standards of quality and safety of medicinal products.
- Category 2 and 3 data in the context of the establishment, operation and maintenance of the EV SSA platform can be based on Article 5(1)(a) of the EUDPR as the processing is necessary for the performance of a task carried out in the public interest. This includes the processing of personal data for the purpose of identity and access management and user authentication and the provision of technical support services, where data concerning health will be masked.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

[15] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
[16] Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council
[17] Guideline on good pharmacovigilance practices (GVP): Module IX – Signal management (Rev. 1)
[18] Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials

2.3. Transfer of personal data outside of EU

The data centres hosting the EV SSA platform are located in the EU i.e., EU-central-1 (Frankfurt, Germany region). This includes data backups, which will be spread across Multiple Availability Zones in the same region.

To maintain the EV SSA platform, for security reasons and to offer technical and end user support, the processor's support engineers may need remote access from outside the EEA, i.e., from the U.S. and India.

EMA has implemented the Oracle Virtual Private Database (OVPD) policy which ensures that support engineers cannot view category 1 personal data.

The personal data in scope of security, technical and end user support can be the following:

Personal Data Category	Description
Category 2	– First and last name and email address of the authorised EV SSA platform user. – Session cookies – IP address – Operating System – Browser – Timestamp (UTC) – All user generated events
Category 3	– First and last name and email address of the authorised EV SSA platform user and/or EMA technical support staff. – Optional: business phone, mobile phone, photo, title, language, time zone, date format, Department and Service, Office / location, manager, contract type (staff or contractor).

Personal data transfers to the U.S. are based on Article 47 of Regulation (EU) 2018/1725 i.e., the processor is certified under the EU-US Data Privacy Framework. For India, an occasional and limited transfer of personal data may take place based on Article 50(d) of Regulation (EU) 2018/1725 i.e., the transfer is necessary for important reasons of public interest.

3. How long do we keep your data?

Personal Data Category	Retention Period
Category 1	• For the duration of the operation of the EV system i.e., there is a legal obligation for EMA to operate and maintain EV for the purpose of safety monitoring of medicines in the pre- and post-authorisation phase.
Category 2	• Your account data will be deleted after 180 days of inactivity on EMA systems (i.e. if you do not use your account on any of EMA's

Personal Data Category	Retention Period
	systems). You will receive a reminder before your data are deleted.
Category 2	• EV SSA application logs are configurable and will be maintained for 90 days. • Infrastructure logs will be maintained for six months and will include personal data of the processor's personnel only.
Category 3	• 3 years from the date of the service being requested.

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

Personal Data Category	Access
Category 1	• Pharmacovigilance and safety experts at EMA, NCAs in Member States and appointed independent experts of the EC in accordance with the EudraVigilance Access Policy
Category 2	• Authorised EMA personnel • Authorised support engineers of the processor
Category 3	• Authorised EMA service desk personnel • Authorised support engineers of the processor

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 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.
- **Right not to be subject to automated decision making** – You have the right to not to be subject to a decision based solely on automated processing if such decision has legal effect on you.

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 Datacontroller.HumanMedicines@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