EMA/83326/2024
1 December 2025

Records of data processing activity (public)

Name and reference number of processing operation: EudraVigilance Signal and Safety Analytics (EV SSA) platform

1.	Last update of this record, version number:	Version. 1
2.	Reference number:	EMA-H-013
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Human Medicines Division Contact: Datacontroller.HumanMedicines@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	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 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 responsibilities are outlined in the JCA. It is to be noted that marketing authorisation holders and sponsors of clinical trials of ICSRs held in the EV SSA platform

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		are separate controllers for their personal data processing activities carried out pursuant to the applicable pharmacovigilance and clinical trials legislation.
6.	Name and contact details of processor (where applicable)	The contact details of the vendor acting as data processor are the following: RxLogix Corporation: 20801 Biscayne Boulevard, Suite 302, Aventura, Florida 33180, USA
7.	Purpose of the 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[1] and Article 40(1) of Regulation (EU) No 536/2014[2]. • 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[3] and clinical trials legislation[4] as well as the good pharmacovigilance practice guidance (GVP) Module VI[5].

[1] 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.
[2] 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.
[3] Article 28 of the Commission Implementing Regulation (EU) 520/2012 and Regulation No (EU) 536/2014
[4] Annex III of Regulation (EU) No 536/2014
[5] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)

8.	Description of categories of persons whose data EMA processes and list of data categories	In this processing operation EMA processes the following personal data: **Category 1** • Personal data and data concerning health of ICSRs reported to EudraVigilance by NCAs in Member States, marketing authorisation holders (MAHs) and sponsors of clinical trials. These data are pseudonymised 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. The pseudonymisation of personal data is described in Module VI Addendum II – Masking of Personal Data in Individual Case Safety Reports Submitted to EudraVigilance. • 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).
9.	Time limit for keeping the data	**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 systems). You will receive a reminder before your data are deleted. • 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 data of the service being requested.
10.	Recipients of the data	Personal Data Category and 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
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	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 and 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(1)(d) of Regulation (EU) 2018/1725 i.e., the transfer is necessary for important reasons of public interest.
12.	General description of security measures, where possible.	The Agency implements appropriate technical and organisational measures to ensure the security of processing personal data in EV pursuant to Article 33 of Regulation (EU) 2018/1725. Each Party implements appropriate organisational measures to ensure the security of processing pursuant to Article 33 of Regulation (EU) 2018/1725 and Article 32 of Regulation (EU) 2016/679, respectively. Access to personal data stored in the in the secure, access-controlled domain of EV undergoing joint processing are only allowed to authorised staff/personnel/authorised users of the Parties acting as data processors, for the purposes of administering, operating and using the IT system which facilitates the processing operation.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement Here you may find the data protection notice regarding this specific data processing operation as well.