EMA/336722/2019

Record of data processing activity for EudraVigilance Human[1,2] (public)

1.	Last update of this record, version number:	07/06/2022, version 2
2.	Reference number:	TDA1
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Data Analytics and Methods Task Force & Head of Pharmacovigilance Department Contact: datacontroller.analytics@ema.europa.eu
4.	Name and contact details of Data Protection Officer:	Contact: dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	The European Medicines Agency (hereafter referred to as "the Agency"), the European Commission (EC) and National Competent Authorities (NCAs) in Union Member States jointly determine the purposes and means of processing personal data in EudraVigilance in accordance with the provisions set out in the pharmaceutical legislation[3]. Therefore, they are deemed "joint controllers" of EudraVigilance in accordance with Article 28 of the Union Data Protection Regulation (EUDPR)[4] and Article 26 of the General Data Protection Regulation (GDPR)[5]. The directory of medicines agencies established in Union Member States can be accessed via the Heads of Medicines Agencies website. The contact details of the EC, Directorate-General SANTE - Health and Food Safety, are accessible as follows:

[1] EudraVigilance
[2] EDPS Opinion 2008-402, available: https://edps.europa.eu/sites/edp/files/publication/09-09-07_emea_eudravigilance_en.pdf
[3] EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use
[4] Regulation (EU) 2018/1725 of the European Parliament and 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).

		https://ec.europa.eu/info/departments/health-and-food-safety_en Furthermore, a list contact points is provided in Annex I to the EudraVigilance Human Joint Controllership Arrangement.
6.	Name and contact details of processor (where applicable)	The Agency may engage third parties in support of the: • Maintenance of EudraVigilance functionalities, • Development of EudraVigilance functionalities, • Monitoring of a number of substances and selected medical literature to identify suspected adverse reactions with medicines authorised in the EU, and for entering the relevant information into EudraVigilance[6], • Management of duplicated Individual Case Safety Reports (ICSRs) submitted to EudraVigilance[7], • Assurance of data quality in EudraVigilance, • Provision of system support to EudraVigilance users. Contact details of the EMA processors can be made available to the data subjects upon request.
7.	Purpose of the processing	The purpose of the EudraVigilance data processing activities can be summarised as follows: **Area of system administration and maintenance** • User registration and access management; • Recording of contact details of the Qualified Person Responsible for Pharmacovigilance; • Maintenance of EudraVigilance including responsibility for data storage; • Ensuring technical support to all users of EudraVigilance in case of troubleshooting. **Area of pharmacovigilance[8]** • Electronic submission of ICSRs by NCAs and MAHs containing information on suspected adverse reactions related to medicines as initially reported by patients[9], healthcare professionals or other sources;

[6] Monitoring of medical literature and entry of adverse reaction reports into EudraVigilance
[7] Guideline on good pharmacovigilance practices (GVP) Module VI Addendum I – Duplicate management of suspected adverse reaction reports (EMA/405655/2016)
[8] Pharmacovigilance: Overview
[9] Did you know? You can report side effects yourself

		• Rerouting of ICSRs reported by MAHs and sponsors[10] to NCAs in Member States where the suspected adverse reactions occurred; • Conduct of searches and generation of reports (e.g., electronic reaction monitoring reports and signal detection), based on data held in EudraVigilance, including extraction and analysis of this data; • Publishing information on reports of suspected adverse reactions on the adrreports.eu portal; • Sharing of information on suspected adverse reactions with the World Health Organisation in accordance with Article 28c(1) of Regulation (EC) No 726/2004. • **Area of clinical trials[11]** • Electronic submission of ICSRs by sponsors containing information on suspected unexpected serious adverse reactions (SUSARs) related to investigational medicinal products (IMPs) studied in clinical trials; • Rerouting of SUSARs reported by sponsors to NCAs in Member States in accordance with the SUSAR rerouting criteria defined by NCAs. • Conduct of searches by NCAs and generation of reports (e.g., safety monitoring) based on data held in EudraVigilance, including extraction and analysis of this data. • **Literature monitoring[12]** • Creating, submitting, recording and storing of ICSRs by the Agency resulting from the selected medical literature monitoring obligations as set out in Article 27 of Regulation (EC) No 726/2004; • **Duplicate and data quality management[13]** • Detecting and managing duplicates of ICSRs submitted by multiple senders by the Agency; • Creating of master cases based on confirmed duplicates by the Agency; • Recoding of medicinal product reported in ICSRs against the Extended Medicinal Product Dictionary (XEVMPD) by the Agency;

[10] It should be noted that Article 42(3) of Regulation (EU) 536/2014 states that where a sponsor, due to a lack of resources, does not have the possibility to report to the database referred to in Article 40(1) and the sponsor has the agreement of the Member State concerned, it may report to the Member State where the suspected unexpected serious adverse reaction occurred. That Member State shall report the suspected unexpected serious adverse reaction in accordance with paragraph 1 of this Article.
[11] Clinical trials in human medicines
[12] Monitoring of medical literature and entry of adverse reaction reports into EudraVigilance
[13] http://www.adrreports.eu/en/data_quality.html

		• Reviewing of data quality of ICSRs by the Agency.
8.	Description of categories of persons whose data EMA processes and list of data categories	The type of categories of persons whose data the Agency processes can be summarised as follows: **a. Administrative information** • Name and contact details of authorised users accessing EudraVigilance; • Contact details of the Qualified Person Responsible for Pharmacovigilance. **b. Area of pharmacovigilance:** • Information on ADRs originating from patients, healthcare professionals and other sources which is submitted by NCAs and MAHs to EudraVigilance. **c. Area of clinical trials:** • Information on SUSARs originating from clinical trials, which is submitted by sponsors to EudraVigilance for evaluation by NCAs whether an IMP poses an unknown risk to the trial subject and to take measures to protect the safety of trial subjects, if necessary. For points b and c, NCAs, MAHs and sponsors of clinical trials pseudonymise information before submission to EudraVigilance, while ensuring that reports still contain sufficient information to allow for the safety monitoring and assessment of medicines.
9.	Time limit for keeping the data	Pseudonymised reports of suspected adverse reactions are maintained for as long as EudraVigilance is in operation in accordance with Article 24(1) of Regulation No 726/2004. This is to provide for a large and coherent data pool covering a wide range of medicinal products and ICSRs, which is necessary to ensure that statistical methods and algorithms for signal detection and data analysis operate consistently and a full and complete scientific evaluation across different medicinal products and therapeutic areas is provided for over time.
10.	Recipients of the data	**a. Area of pharmacovigilance** The provisions for access to EudraVigilance data and the actors, to whom access should be granted, are set out in the pharmaceutical legislation[14]. The EudraVigilance Access Policy[15] further details the different levels of access provided to these actors taking into account the need to protect personal data as well as their pharmacovigilance and safety monitoring obligations or interests. These actors refer to NCAs in Union

[14] Article 24(2) of Regulation (EC) No 726/2004
[15] European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (EudraVigilance Access Policy) (EMA/759287/2009 Revision 3*)

		Member States, the EC, the Agency, healthcare professionals, the public, MAHs, academia, the World Health Organisation (WHO) and medicines and regulatory authorities in third countries. Pseudonymised information on spontaneous reports from patients and healthcare professionals in EudraVigilance can be accessed publicly as follows: adrreports.eu. **b. Area of clinical trials** In accordance with Regulation (EU) No 536/2014, access to SUSARs reported to EudraVigilance is provided to NCAs in Member States of the EU/EEA, the Agency and the EC.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Reports of suspected adverse reactions submitted to EudraVigilance Human may be shared with regulatory authorities and international organisations of third countries based on mutual cooperation agreements or confidentiality arrangements and in accordance with EudraVigilance Access Policy. Please see also point 10. Staff of the processor detailed in section 6 may be located at premises outside the EEA. Access to EudraVigilance is granted to authorised personnel of the processor and restricted to the purposes outlined under point 7. Any transfer to third countries is performed in compliance with of Chapter V of Regulation (EU) 2018/1725.
12.	General description of security measures, where possible.	EudraVigilance is kept in a secure electronic environment designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored. Data may only be changed or deleted by authorised persons using a username and password. Authorisation is given at senior management level and based on business needs. The Agency has put in place adequate measures to prevent, detect and address any potential security breaches. Non-public access is based on an organisation and user identity and authorisation management system[16]. Authorised users are required to cooperate in ensuring the security of EudraVigilance and the protection of personal data thereof in line with their legal obligations. The security principles and responsibilities are set out in a best practice guide[17] published on the EudraVigilance webpage[18].
13.	For more information, including how to exercise your rights to access,	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-

[16] EudraVigilance: how to register
[17] Information security using the EudraVigilance system. Best practice guide for management of authorised access to EudraVigilance.
[18] EudraVigilance: security principles and responsibilities.

	rectification, object and data portability (where applicable), see the privacy statement:	privacy-statement, where you may find the EMA General Privacy Statement as well as the data protection notice on the specific EudraVigilance Human data processing operations.