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Record of data processing activity for EudraVigilance Human (public)

1.	Last update of this record, version number:	2.1
2.	Reference number:	TDA1
3.	Name and contact details of controller:	European Medicines Agency (EMA) Internally: Head of Data Analytics and Methods Task Force & Head of Human Medicines Division Contact: datacontroller.analytics@ema.europa.eu 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) under the Joint Controllership Arrangement (JCA)	Together with EMA, the European Commission (DG SANTE) and National Competent Authorities in Member States of the EU/EEA act as joint controllers for the purpose of processing operations of personal data in EV as documented in the Joint Controllership Arrangement. The contact points of the joint controllers are the following: • **European Commission:** sante-consult-b5@ec.europa.eu • **Member States:** see Annex I of the JCA The respective roles and relationship vis-à-vis data subjects are also explained in the JCA. MAHs and sponsors of clinical trials are controllers in their own rights for their personal data processing activities carried out pursuant to the pharmacovigilance and clinical trials legislation, as applicable. For instance, MAHs act as controllers in their own rights when reporting suspected adverse

		reactions[1] and accessing EudraVigilance to comply with their pharmacovigilance obligations[2] and sponsors of clinical trials when they report suspected unexpected serious adverse reactions (SUSARs)[3].
6.	Name and contact details of processor (where applicable)	The Agency engages third parties to provide support for the: • maintenance of EV functionalities, • development of EV functionalities, • monitoring of several substances and selected medical literature to identify suspected adverse reactions with medicines authorised in the EU, and for entering the relevant information into EV,[4] • management of duplicated ADR reports submitted to EV[5], • assurance of data quality in EV, • provision of system support to EV users. Personal data may be disclosed to the third parties acting as data processors of personal data processed in the context of EudraVigilance. Contact details of the EMA processors and contact details of the processors of the other joint controllers can be made available upon request.
7.	Purpose of the processing	The purpose of the EV data processing activities can be summarised as follows: • User registration and access management; • Maintenance of EV including responsibility for data storage; • Ensuring technical support to all users of EV in case of troubleshooting; **a. In the area of pharmacovigilance:** • Electronic submission of Individual Case Safety Reports (ICSRs) by NCAs and MAHs containing information on suspected adverse reactions related to medicines as initially reported by patients,[6] healthcare professionals or other sources; • Rerouting of ICSRs reported by MAHs to NCAs in Member States where the suspected adverse reactions occurred; • Conduct of searches and generation of reports (e.g., safety monitoring and signal detection), based on data held in EV, including extraction and analysis of this data outside of the system by authorised users; • Publishing information on reports of suspected adverse reactions on the adrreports.eu portal; • Enabling access to MAHs to fulfil their pharmacovigilance obligations; • Sharing of information on suspected adverse reactions with the World Health Organization(WHO) – Uppsala Monitoring Centre (UMC) in accordance with Article 28c(1) of Regulation

[1] In accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107 of Directive 2001/83/EC
[2] In accordance with Article 24(2) of Regulation (EC) No 726/2004
[3] In accordance with Article 42(1) of Regulation (EU) No 536/2014
[4] Medical literature monitoring | European Medicines Agency (EMA)
[5] Guideline on good pharmacovigilance practices (GVP) - Module VI Addendum I – Duplicate management of suspected adverse reaction reports
[6] ADR_reporting_FINAL_EN.pdf

		(EC) No 726/2004 and agreed modalities for the transfer of such information[7]. **b. In the area of clinical trials:** • Electronic submission of ICSRs by sponsors and/or NCAs containing information on 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 previously defined by the NCAs; • Conduct of searches by NCAs and generation of reports (e.g., safety monitoring) based on data held in EV, including extraction and analysis of this data outside of the system by authorised users. **c. In the area of Medical Literature Monitoring (MLM):** • 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. **d. In the area of duplicate detection and data quality management** • Detecting and managing duplicates of ICSRs submitted by multiple senders by the Agency; • Creating master cases based on confirmed duplicates by the Agency; • Making available medicinal product information in Extended Medicinal Product Dictionary (XEVMPD) and recoding of medicinal product information reported in ICSRs against the XEVMPD by the Agency; • Reviewing of data quality of ICSRs by the Agency.
8.	Description of categories of persons whose data EMA processes and list of data categories	Personal data refer to 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 an identifier such as name, an identification number or others.[8] The content of ICSRs is defined by legislation[9] with the minimum reporting criteria further set out in good pharmacovigilance practice guidance (GVP) Module VI[10] and Regulation 536/2014. Examples of personal data that can be processed by NCAs, MAHs and sponsors of clinical trials for the reporting of suspected adverse reactions are name, address or phone number of a healthcare professional/investigator, a patient's email address (name.surname@xxxx.com) or details regarding an identified or identifiable patient's health or personal characteristics (e.g., age, gender). NCAs, MAHs and sponsors of clinical trials pseudonymise such information before submission to EV, while ensuring that reports still contain sufficient information to allow for the safety monitoring and assessment of medicines. Pseudonymisation means the

[7] World Health Organization (WHO) | European Medicines Agency (EMA)
[8] Definition in accordance with Article 3(1) of 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).
[9] Article 28 of the Commission Implementing Regulation (EU) 520/2012 and Regulation No (EU) 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)

		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[11]. NCAs, MAHs and sponsors of clinical trials assign a unique identifier to each ICSR so they can follow-up reports and when submitted to EV, the ICSRs can be adequately processed, and duplicates detected and managed. Rules are in place prohibiting re-identification of data subjects with the exception where NCAs, MAHs or sponsors of clinical trials need to follow-up with the initial reporter of the suspected adverse reaction(s). GVP Module VI[12] also sets out the obligations as regards the monitoring of public sources such as medical literature, internet or digital media including social media. This may involve the processing of personal data as part of ADR reports originating from such public sources, which are important to support the monitoring of the safety and the risk-benefit balance of medicinal products, particularly in relation to the detection of new safety signals or emerging safety issues.
9.	Time limit for keeping the data	Pseudonymised reports of suspected adverse reactions are maintained for as long as EV 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	The provisions of access to EV data and the actors, to whom access should be granted, are set out in the pharmaceutical legislation.[13] The EV Access Policy[14] 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 obligations or interests. These actors, potential recipients of personal data, refer to NCAs in Union Member States, the European Commission, the Agency, healthcare professionals, the public, MAHs, academia, the World Health Organization (WHO) – Uppsala Monitoring Centre (UMC) and in exceptional circumstances to medicines and regulatory authorities in third countries. Personal data may also be disclosed to the private entities acting as data processors of personal data in the context of EudraVigilance (see section 6 Who are the data processors). Information on spontaneous reports from patients and healthcare professionals held in EV can be accessed publicly as follows: https://www.adrreports.eu/en/index.html In accordance with Regulation (EU) No 536/2014, access to SUSARs reported to EVCTM is provided to NCAs in Member States of the EU/EEA, the Agency and the Commission.
11.	Are there any transfers of personal data to third	The data centers hosting EV are located in the following EU countries: Netherlands and Germany.

[11] Article 3(6) of Regulation (EU) 2018/1725.
[12] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[13] Article 24(2) of Regulation (EC) No 726/2004 Regulation (EC) No 726/2004
[14] European medicines Agency policy on access to EudraVigilance data for medicinal products for human use (EudraVigilance Access Policy) EMA/759287/2007 Revision 4* European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use

	countries or international organisations? If so, to which ones and with which safeguards?	Where personal data is made available to the public via the adrreports.eu portal and is accessed from outside the EU/EEA, this is based on Article 50(1)(g) of Regulation (EU) 2018/1725, or Article 49(1)(g) of Regulation (EU) 2016/679, i.e. the transfer is made from a register which, according to Union law, is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down in Union law for consultation are fulfilled in the particular case. If a joint controller authorises a user to access the secure, access-controlled domain of EV from outside the EU/EEA, that joint controller shall ensure that an appropriate data transfer mechanism is established prior to any access by that user, and that such international data transfer complies with the rules of Chapter V of Regulation (EU) 2018/1725 or Regulation (EU) 2016/679, as applicable. The appropriate data transfer mechanism may refer to an adequacy decision,[15] appropriate safeguards[16] or a derogation.[17] MAHs and sponsors of clinical trials, who act as controllers in their own rights, are responsible for managing their users in EudraVigilance. The qualified person responsible for pharmacovigilance[18] of MAHs or the responsible person for EudraVigilance for sponsors of clinical trials may grant access to EudraVigilance to authorised personnel located outside the EU/EEA. In this case, the MAH/sponsor of clinical trials is responsible for establishing an appropriate data transfer mechanism prior to any access by users located outside of the EU/EEA and that such international data transfers comply with the rules of Chapter V of Regulation (EU) 2016/679. Access to case narratives by MAHs is granted on an ad hoc basis and subject to a confidentiality undertaking[19] (Annex C of the EudraVigilance Access Policy), which sets out the data protection and confidentiality obligations of users of MAHs. Whilst it is recognised that MAHs may be subject to adverse reaction reporting obligations outside the EEA, the confidentiality undertaking requires MAHs to "ensure that personal data reported can no longer be attributed to a specific data subject".
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[20]. 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

[15] As defined in Article 47 of Regulation 2018/1725 and Article 45 of Regulation 2016/689 as applicable.
[16] As defined in Article 48 of Regulation 2018/1725 and Article 46 of Regulation 2016/689 as applicable.
[17] As defined in Article 50 of Regulation 2018/1725 and Article 49 of Regulation 2016/689 as applicable.
[18] As part of the pharmacovigilance system, the marketing authorisation holder shall have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance in the EU (QPPV) [DIR Art 104(3)(a)].
[19] European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use, Annex C – Confidentiality undertaking for marketing authorisation holder, EMA/337295/2016, EudraVigilance Access Policy - Confidentiality undertaking for marketing authorisation holders
[20] EudraVigilance: how to register | European Medicines Agency (EMA)

		out in a best practice guide[21] published on the EudraVigilance webpage[22].
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 personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/data-protection-privacy-ema Here you may find the data protection notice regarding this specific data processing operation as well.

[21] EudraVigilance: security principles and responsibilities | European Medicines Agency (EMA)
[22] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-security-principles-responsibilities