European Medicines Agency's Data Protection Notice for EudraVigilance Human (EV)

This Data protection notice explains the most essential details of the processing of personal data in the context of the operation of EudraVigilance Human (EV) established in accordance with the requirements of Article 24(1) of Regulation (EU) No 726/2004[1]. The European Medicines Agency (hereafter referred to as "the Agency"), in collaboration with Union Member States and the European Commission, has set up and maintains the EudraVigilance database and data processing network[2] to collate and analyse information on suspected adverse reactions regarding investigational medicinal products (IMPs) studied in clinical trials and medicinal products authorised in the EU. This is to allow national Competent Authorities (NCAs), the Agency and the Commission to access and share that information simultaneously. Whilst EV is operated by the Agency, its content originates from NCAs, marketing authorisation holders (MAHs) and sponsors of clinical trials.

This Data Protection Notice explains the most essential details of the processing of personal data by the Agency, which includes:

- the area of **pharmacovigilance**[3] and information on suspected adverse drug reactions (ADRs) originating from patients, health care professionals and other sources, which is reported to EV by NCAs and MAHs, thus supporting the continuous safety of medicines[4];
- the area of **clinical trials**[5] and information on suspected unexpected serious adverse reactions (SUSARs) reported by sponsors[6] to EV thus allowing NCAs to evaluate whether an IMP poses an unknown risk to the trial subject and to take measures to protect the safety of trial subjects, if necessary[7].

The joint controllers ensure that processing of personal data in the context of the operation of EV complies with all applicable requirements of Regulation (EU) 2018/1725[8] (EUDPR) and Regulation (EU) 2016/679[9] (GDPR), respectively, and other applicable national rules on data protection.

[1] CL2004R0726EN0080010.0001.3bi_cp 1..1 (europa.eu)
[2] EudraVigilance | European Medicines Agency (europa.eu)
[3] Pharmacovigilance: Overview
[4] Title IX, Chapter 3 of Directive 2001/83/EC, Title II, Chapter 3 of Regulation (EC) 726/2004 and Chapters III, IV and V of the Commission Implementing Regulation (EU) 520/2012
[5] CHAPTER VII SAFETY REPORTING IN THE CONTEXT OF A CLINICAL TRIAL of Regulation 536/2014
[6] 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.
[7] Regulation (EU) No 536/2014
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN
[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

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1. Who is responsible for your data?

1.1. Who are the joint controllers?

The joint controllers under the Joint Controllership Arrangement (JCA) are the European Medicines Agency, the European Commission and National Competent Authorities in Member States of the EU/EEA.

The Parties of the Joint Controllership Arrangement act as joint controllers for the purpose of processing operations in EV of personal data provided in structure data and supporting documents.

The contact points of the joint controllers are the following:

- **European Medicines Agency:** datacontroller.analytics@ema.europa.eu
- **European Commission:** sante-consult-b5@ec.europa.eu
- **Member States:** Annex I of the JCA

The respective roles and relationship vis-à-vis data subjects are explained in the JCA. In accordance with the applicable rules of the EUDPR and GDPR, data subjects may exercise their rights under the Regulations in respect of, and against each of, the joint controllers. In order to ensure that any request can be handled as swiftly as possible, it is recommended that data subject contacts the joint controller who, in line with the activities allocated in the JCA, collected, and mainly processes the personal data concerned.

It should be noted that marketing authorisation holders and sponsors of clinical trials are separate controllers for their personal data processing activities carried out pursuant to the pharmacovigilance and clinical trials legislation, as applicable.

1.2. Who is the data processor?

The Agency engages third parties to provide support for the:

- maintenance of EV functionalities,
- development of EV 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 EV[10],
- management of duplicated ADR reports submitted to EV[11],
- assurance of data quality in EV,
- provision of system support to EV users.

Contact details of the EMA processors (and, if necessary, of other Parties' processors), can be made available to the data subjects upon request.

[10] Monitoring of medical literature and entry of adverse reaction reports into EudraVigilance

[11] Guideline on good pharmacovigilance practices (GVP) Module VI Addendum I – Duplicate management of suspected adverse reaction reports (EMA/405655/2016)

2. Purpose of this data 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[12], 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 (see section 4);
- 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 and agreed modalities for the transfer of such information[13].

b. In the area of clinical trials:

- Electronic submission of ICSRs by sponsors and/or NCAs 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 to 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 (see section 4).

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;

[12] Did you know? You can report side effects yourself
[13] World Health Organization (WHO) | European Medicines Agency (europa.eu)

- Reviewing of data quality of ICSRs by the Agency.

2.1. Categories of personal data concerned

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[14].

The content of ICSRs is defined by legislation[15] with the minimum reporting criteria further set out in good pharmacovigilance practice guidance (GVP) Module VI[16] 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 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[17].

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[18] 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.

2.2. Legal Basis

EV related personal data processing operations are expressly provided for in the pharmaceutical legislation[19] and in relevant national provisions and are necessary for the performance of tasks carried out in the public interest. They refer the purpose of the protection of health by setting standards of quality and safety for medicinal products. In particular, the processing of data is provided for under:

[14] 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)
[15] Article 28 of the Commission Implementing Regulation (EU) 520/2012 and Regulation No (EU) 536/2014
[16] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[17] Article 3(6) of Regulation (EU) 2018/1725.
[18] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[19] EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use

- Title II, Chapter 3 of Regulation (EC) No 726/2004[20] as regards the pharmacovigilance obligations for centrally authorised medicinal products;
- Title IX, Chapter 3 of Directive 2001/83/EC[21] and the obligations for the recording, reporting and assessment of pharmacovigilance data relating to non-centrally authorised medicinal products;
- Chapter VII of Regulation (EU) No 536/2014 and the obligations relating to the performance of safety reporting and assessment;
- Chapter IV[22] of the Commission Implementing Regulation (EC) No 520/2012, which sets out the rules on the format and content for the submission of reports of suspected adverse reactions and Chapter V[23] lays down the principles for the transmission of reports of suspected adverse reactions including the content of such reports;
- Chapter III[24] of the Commission Implementing Regulation (EC) No 520/2012, which defines the minimum requirements for the monitoring of data in the EV database with further details on the signal management process provided for in GVP Module IX[25]
- Chapter II of the Commission Implementing Regulation (EU) 2022/20, which describes the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials

The processing operations which are necessary for compliance with a legal obligation to which the joint controllers are subject to can therefore be justified under Article 5(1)(b) of the EUDPR and Article 6(1)(c) of the GDPR and the corresponding appropriate condition for lawful processing of special categories of data in the context of these obligations is Article 10(2)(i) of the EUDPR and Article 9(2)(i) of the GDPR.

2.3. Transfer of personal data outside of EU

The data centres used for EV are stored in the following EU countries: Netherlands, Ireland, and Germany. 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 Party authorises a user to access the secure, access-controlled domain of EV from outside the EU/EEA, that Party shall ensure that an appropriate data transfer mechanism is established prior to any access by that user, and that such international data transfers comply with the rules of Chapter V of Regulation (EU) 2018/1725 or Regulation (EU) 2016/679, respectively.

[20] Title II "Authorisation and supervision of medicinal products for human use", Chapter 3 "Pharmacovigilance" of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
[21] Title IX "Pharmacovigilance", Chapter 3 "Recording, reporting and assessment of pharmacovigilance data" of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2 DIRECTIVE 2001/83/EC on the Community code relating to medicinal products for human use.
[22] CHAPTER IV "Use of terminology, formats and standards" Commission Implementing Regulation (EU) 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.
[23] CHAPTER V "Transmission of reports of suspected adverse reactions" Commission Implementing Regulation (EU) 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.
[24] CHAPTER III "Minimum requirements for the monitoring of data in the Eudravigilance database", Commission Implementing Regulation (EU) 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.
[25] Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management (Rev 1).

3. How long do we keep your 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.

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

The provisions of access to EV data and the actors, to whom access should be granted, are set out in the pharmaceutical legislation[26]. The EV Access Policy[27] 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 refer to NCAs in Union Member States, the European Commission, the Agency, healthcare professionals, the public, MAHs, academia, the WHO and medicines and regulatory authorities in third countries.

Information on spontaneous reports from patients and healthcare professionals held in EV can be accessed publicly as follows: adrreports.eu.

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.

5. What are your rights under personal data protection?

Data subjects (i.e., the individual whose personal data is processed) have a number of rights:

- **Right to be informed** – This data protection notice provides information on how the joint controllers, via EV, collect and use personal data. Requests for other information regarding the processing may also be directed to datacontroller.analytics @ema.europa.eu
- **Right to access** – Data subjects have the right to access their personal data. Data subjects have the right to request and obtain a copy of the personal data processed regarding them.
- **Right to rectification** – Data subjects have the right to obtain - without undue delay - the rectification or completion of their personal data if it is incorrect or incomplete.
- **Right to erasure** – Data subjects have the right to require the Agency to delete or stop processing their personal data, for example where the data is no longer necessary for the purposes of processing. In certain cases, the data may be kept to the extent it is necessary, for example, to comply with a legal obligation or if it is necessary for reasons of public interest in the area of public health.

  In cases where the right to erasure is requested and granted to a data subject, data may be kept if it has undergone an appropriate process of anonymisation.
- **Right to restrict processing** – In a few, codified cases, Data subjects have the right to obtain the restriction of the processing, meaning that their data will only be stored, but not actively processed for a limited period of time. For more information about this right and its

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

limitations, see the EMA General Data protection notice, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement

In the context of the right to access and the right to rectification, you should note that there may be instances where a requestor contacts the Agency as regards their personal data being processed in EV, but it may not be possible for the Agency to confirm whether personal data concerning the requestor are being processed. This is based on the principle that generally personal data in ICSRs are pseudonymised before being submitted by an NCA, a MAH or a sponsor to EV (as outlined in section 3.1). In such instances, the Agency will refer the requestor to the NCA, MAH or sponsor that submitted the ICSR to EV, who may in turn refer them to their healthcare professional/investigator, who submitted the report.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725[28].

6. Recourse

In case data subjects have any questions regarding the processing of their personal data, or they think that the processing is unlawful, or it is not in compliance with this Data Protection Notice or the general EMA Data Protection Notice, the joint controllers can be contacted via the contact points listed in Section 1.1.

Data subjects also have the right to lodge a complaint with the European Data Protection Supervisor (EDPS) at any time at the following address: edps@edps.europa.eu
or with a competent Data Protection Authority whose contact details you may find here: https://edpb.europa.eu/about-edpb/board/members_en

[28] 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)