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Inspections, Human Medicines Pharmacovigilance & Committees Division

European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use

(EudraVigilance Access Policy)

Start of public consultation	4 August 2014
End of public consultation	15 September 2014
Final draft agreed by Project Team 1 "Collection of key information on medicines" of the EMA/Member States governance structure for the implementation of the pharmacovigilance legislation	September 2015
Final draft submitted to the EudraVigilance Expert Working Group for information	23 September 2015
Final draft agreed by Pharmacovigilance Risk Assessment Committee (PRAC)	5-8 October 2015
Final draft agreed by Project Co-ordination Group of the EMA/Member States governance structure for the implementation of the pharmacovigilance legislation	12 October 2015
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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

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Update of data protection legislation references*	23 August 2019

*** Revision 4: update of references in accordance with Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) and Regulation (EU) 2018/1725, the EU Data Protection legislation (EU DPR).**

Revision 3 referred to a minor technical update of Annex B based on experience gained:

Level 1 - public access via the adrreports.eu portal - data elements C.1.8.1 and C.3.2

ICH/EU Field	Header Element	Data Element	Field Name	Revision 3 Level 1 – public access	Explanation
ICH	C.1	C.1.8.1 (page 38)	**Worldwide Unique Case Identification**	Displayed as “EudraVigilance Local Report Number” at the adrreports.eu portal	Many organisations are using a country code and/or an organisation abbreviation, which may contain country information as part of the “Worldwide Unique Case Identifier” that is assigned to an individual case. For data privacy reasons and to avoid the risk of patient/reporter re-identification, the “EudraVigilance Local Report Number” is

ICH/EU Field	Header Element	Data Element	Field Name	Revision 3 Level 1 – public access	Explanation
					therefore displayed at the adrreports.eu portal for the public. The “EudraVigilance Local Report Number” is assigned by the EudraVigilance system and is an alphanumeric code without semantic information.
ICH	C.3	C.3.2 (page 41)	**Sender’s organisation**	Displayed as "EEA Regulator" when the Sender Type=2 “Regulatory Authority” or Sender Type = 4 “Regional Pharmacovigilance Centre” at the adrreports.eu portal	Displaying the name of the sender organisation for an EEA regulatory authority or a regional pharmacovigilance centre can potentially allow for the identification of the country of occurrence of the suspected adverse reaction. For data privacy reasons “EEA Regulator” is therefore displayed at the adrreports.eu portal where the sender type is “Regulatory Authority” or “Regional Pharmacovigilance Centre”.

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Executive Summary

The European Medicines Agency (hereafter referred to as “the Agency”) and the medicines regulatory authorities collectively comprise the European Union (EU) regulatory network. The network's responsibilities are the protection and promotion of public health through the evaluation and supervision of medicines and the continuous safety monitoring and benefit-risk assessment of medicines, including the collection, management and dissemination of information on suspected adverse reactions to medicines (pharmacovigilance). The key EU resource to support this activity is EudraVigilance, a centralised European database of suspected adverse reactions related to medicinal products authorised in the European Economic Area (EEA).

In December 2010, the EMA Management Board adopted a EudraVigilance Access Policy, which came in force in July 2011. This policy outlined the data elements for and the principles of providing access to reports of suspected adverse reactions referred to as Individual Case Safety Reports (ICSRs) in EudraVigilance as regards medicines regulatory authorities and marketing authorisation holders (MAHs) in the EEA, healthcare professionals, patients and consumers (hereafter referred to as “public”) as well as academia.

In the context of this EudraVigilance Access Policy, a proactive and reactive disclosure of ICSR data are identical i.e. the information that is made available is the same irrespectively if the Agency is taking the initiative to make the data accessible through different technical solutions or if a party submits a request to the Agency to obtain such data. This approach is putting the principles of transparency in effect in the sense that maximum data are released proactively, that the needs of stakeholders are met and that the requirements of Union personal data protection legislation, in particular, Regulation (EU) 2018/1725[1], the EU Data Protection Regulation (EU DPR) and Regulation (EU) 2016/679[2], the General Data Protection Regulation (GDPR) are adhered to.

The Agency is granting medicines regulatory authorities in the EEA unrestricted access to all ICSRs held in EudraVigilance. Since May 2012, healthcare professionals, the public, MAHs and academia have certain levels of access to spontaneous reports focusing on centrally authorised medicinal products. This access is provided through the adrreports.eu portal of the Agency and was extended in September 2014 to all active substances contained in medicinal products authorised in the EEA.

The 2010 pharmacovigilance legislation i.e. Regulation (EC) No 726/2004, Directive 2001/83/EC and the Commission Implementing Regulation (EU) No 520/2012 introduced significant changes in the way adverse reactions are to be reported to and accessed in EudraVigilance. Those changes refer in particular to the:

- Empowerment of patients in all EEA Member States to report ICSRs via national spontaneous reporting systems[3];

[1] 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

[2] 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)

[3] Reporting in accordance with Article 107a of Directive 2001/83/EC

- Simplification of the reporting of adverse reaction reports, in particular for MAHs for which EudraVigilance will become a single reporting point in the EEA and the re-routing of ICSRs to the Member States where the adverse reactions occurred;
- Provision of EEA adverse reaction reports to the World Health Organisation (WHO);
- The broadening of EudraVigilance access to MAHs to the extent necessary to fulfil their pharmacovigilance obligations through continuously monitoring of data in EudraVigilance 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 the medicinal product as well as to validate signals as appropriate based on an examination of ICSRs;
- Further increase of transparency on the evaluation of safety issues including those related to suspected adverse reactions based on the publication of agendas and meeting minutes of the Pharmacovigilance Risk Assessment Committee (PRAC) thus allowing stakeholders to follow the discussion and evaluation by the PRAC;
- Enhancements to the EudraVigilance database, which is to be subject to an independent audit;
- The use of internationally agreed formats, standards and terminologies (such as the ISO ICSR format).

Taking into account these important developments, the EudraVigilance Access Policy adopted in December 2010 has been updated whilst maintaining adherence to personal data protection requirements pursuant to the provisions of the EU DPR. The aim is to provide the access necessary for those with legal obligations in pharmacovigilance as well as to give the highest possible degree of transparency while minimising the necessity to engage in ad-hoc individual requests.

The methods by which stakeholders are provided with access to EudraVigilance based on defined ICSR data elements and in accordance with EU data protection legislation have been further elaborated based on experience gained and taking into account the changes introduced by the 2010 pharmacovigilance legislation.

It should be noted that for access to reports of suspected unexpected serious adverse reactions (SUSARs) pursuant to the provisions set out in 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, the provisions of access to the EudraVigilance Clinical Trial Module (EVCTM) as outlined in the EudraVigilance Access Policy adopted in December 2010 currently remain unchanged.

In summary:

- No changes in the EudraVigilance Access Policy have been introduced for the following stakeholders:
  - Medicines regulatory authorities, the Agency and the European Commission, who maintain access to all ICSR data (Section 5.2.5.1. and Table 4);
  - MAHs and sponsors of clinical trials, using EVWEB for the electronic reporting of ICSRs will maintain full access their own reports (Section 5.2.5.3. and Table 6).
- The main changes in the EudraVigilance Access Policy are:

- Healthcare professionals and the public will gain extended access to ICSR data for all medicinal products authorised in the EU by means of easy to use retrieval functions provided through the Agency's adrreports.eu portal (Section 5.2.5.2. and Table 5).
- MAHs will be provided with access to defined ICSR data element sets in support of their signal detection, validation and other pharmacovigilance obligations (Section 5.2.5.3. and Table 6);
- Academia will gain extended access to ICSR data sets in support of their research activities and requests (Section 5.2.5.4. and Table 7.);
- WHO Uppsala Monitoring Centre (UMC) will receive regular electronic data outputs for ICSRs originating from within the EEA (Section 5.2.5.5. and Table 8);
- Medicines regulatory authorities in third countries can obtain data outputs on an ad-hoc basis based on the same data elements as shared with the WHO-UMC (Section 5.2.5.6. and Table 9);
- The need to maintain the confidentiality of the identity of individuals such as patients and reporters in accordance with EU data protection law is being further emphasised including the responsibility of concerned stakeholders to apply appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss (text integrated in the description of access for each stakeholder);
- The data elements for ICSRs have been reviewed and updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide.

1. Background

In line with the 2010 pharmacovigilance legislation (i.e. Regulation (EC) No 726/2004[4], Directive 2001/83/EC[5] as amended and Commission Implementing Regulation (EU) No 520/2012[6]), the Agency is updating and further implementing the EudraVigilance Access Policy that defines the levels of stakeholder access to ICSRs reported to EudraVigilance whilst fully respecting the need to protect personal data as defined by the EU DPR[7] and the GDPR[8].

In 2008, a draft EudraVigilance Access Policy (hereafter referred to as 'Access Policy') was prepared by the EudraVigilance Expert Working Group (EV-EWG) in liaison with the EudraVigilance Steering Committee, Heads of Medicines Agencies and the Agency's Management Board, which was finalised in December 2010 and which came into force in July 2011.

The draft Access Policy was subject to a three months public consultation from December 2008 to March 2009 upon which twenty-two organisations and individuals provided feedback. Furthermore, the European Data Protection Supervisor (EDPS) issued his final Opinion[9] on a "Notification for Prior Checking regarding the data processing operations of EudraVigilance" in September 2009, upon which the Agency made a proposal in December 2009 on how to address the recommendations of the EDPS.

Recommendations[10] of the European Ombudsman (EO) on transparency and openness as regards the Agency's activities for stakeholders to have appropriate levels of access to information, which is easily accessible and user-friendly, were also considered and incorporated.

Taking into account the changes to the pharmacovigilance legislation in 2010 and the technological progress including the ISO ICSR[11] standard and the ICH E2B(R3) [12]/EU ICSR Implementation Guides[13], the Access Policy, has been updated.

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[4] 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

[5] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[6] 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

[7] 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

[8] 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)

[9] Opinion on a Notification for Prior Checking Received from the Data Protection Officer of the European Medicines Agency regarding the EudraVigilance database, Brussels, 7 September 2009 (Case 2008-402)

[10] http://www.ombudsman.europa.eu/press/release.faces/en/4819/html.bookmark.

[11] ISO ICSR 27953-2:2011 Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR

[12] Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html)

[13] EU Individual Case Safety Report (ICSR) Implementation Guide (EMA/51938/2013)

Following agreement by the pharmacovigilance governance and the Pharmacovigilance Risk Assessment Committee (PRAC), a draft of the updated Access Policy was released for public consultation from 4 August 2014 until 15 September 2014. This draft was also circulated on 4 August for consultation to the Committee for Human Medicinal Products (CHMP) and the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMD-h), the EDPS, the EO, the EV-EWG, the Patients' and Consumers' Working Party (PCWP), the Health Care Professional Working Group (HCPWP) and the Heads of Medicines Agencies for Human Medicines (HMA-h). The World Health Organisation – Uppsala Monitoring Centre (WHO-UMC) was also consulted in particular in the context of the preparation of an arrangement on principles of data sharing.

392 interested organisations and individuals provided feedback on the draft Access Policy. All comments were consolidated and reviewed by the Agency and the Access Policy finalised based on the feedback received. An overview of the comments is provided in the document referenced as EMA/649218/2014.

2. Scope

This Access Policy defines the overall principles for providing access to ICSR data held in EudraVigilance in line with the EU legal framework and taking into account that the interest in and the use of the data may vary between stakeholders. Requirements to protect personal data based on the EU DPR as well as the recommendations of the EDPS and the EO were assessed by the Agency and reflected in the policy accordingly.

According to Article 24(1) of Regulation (EC) No 726/2004, the EudraVigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

Article 24(2) of the Regulation defines the level of EudraVigilance access as follows:

- EudraVigilance shall be fully accessible to the competent authorities of the Member States and to the Agency and the European Commission.
- It shall also be accessible to MAHs to the extent necessary for them to comply with their pharmacovigilance obligations.
- The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the EudraVigilance database, while guaranteeing personal data protection.

Article 28c of Regulation (EC) No 726/2004 further states that

- The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the WHO.

Principles of reporting of suspected adverse reactions related to medicines for human use as well as the description of individual cases and ICSRs are further outlined in Annex 0.

For access to reports of suspected unexpected serious adverse reactions (SUSARs) pursuant to the provisions set out in Regulation (EU) No 536/2014[14] of the European Parliament and of the Council of

[14] 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

16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC[15], the provisions of access to the EudraVigilance Clinical Trial Module (EVCTM) as outlined in the EudraVigilance Access Policy adopted in December 2010 currently remain unchanged.

3. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy.
- Characteristics of the policy.
- Date of coming into effect of the policy.

4. Objectives

This Access Policy has been developed with the goal to facilitate the continuous monitoring of the safety of medicines and the evaluation of the benefits and risks of medicines authorised in the EU with the overall aim to promote and protect public health.

Furthermore, the Access Policy aims to meet the EU principles of transparency and openness and to ensure compliance with EU personal data protection legislation. A proactive and reactive disclosure of ICSR data are considered identical i.e. the information that is made available in line with this Access Policy is the same independently of the Agency making the data accessible through different technical solutions or through a request to obtain such data submitted by a party to the Agency. This approach is putting the principles of transparency in effect in the sense that maximum data are released proactively, that the needs of stakeholders are met and that the requirements of Union personal data protection legislation, in particular, the EU DPR and the GDPR are adhered to.

By providing proactive access to adverse reaction data collected in EudraVigilance, the following objectives should be met:

- Providing openness to citizens, who are directly affected by the EU Regulatory Network's decisions relating to the authorisation and supervision of medicinal products, including the monitoring and assessment of the safety of medicines;
- Facilitating the monitoring of the safety of medicines following their authorisation and marketing;
- Supporting signal detection and validation activities related to all authorised medicines in the EU;
- Allowing the use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research;
- Providing promptly all suspected adverse reactions occurring in the EEA to the WHO;
- Strengthening of the collaboration with medicines regulatory authorities in third countries as regards the safety monitoring of medicines.

[15] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Whilst respecting the principles defined in this Access Policy, it should be noted that the level of disclosure of data held in EudraVigilance as part of documents such as Periodic Safety Update Reports and Risk Management Plans and the preparation of assessment reports triggered by regulatory procedures may vary from the data sets defined in this document. As a general principle, an adequate level of redaction of personal data included in the concerned assessment reports and other related documents must be ensured, taking into account the application of Regulation (EC) No 1049/2001[16] concerning access to documents as well as applicable EMA/HMA transparency policies[17].

5. Characteristics of the policy

5.1. EudraVigilance and Medicinal Products for Human Use

EudraVigilance[18] has multiple functions, which relate to the secure electronic transmission of ICSRs, the collection, administration and quality management of these reports in a centralised database, which serves the early detection of potential safety signals and the evaluation thereof. To support these functions, EudraVigilance is composed of the following main system components:

Data processing and management system components

- **EudraVigilance Gateway**, a data-processing network for the secure electronic exchange of adverse reaction data.
- **EudraVigilance Post-Authorisation Module (EVPM)** dedicated to the collection of ICSRs related to all medicinal products authorised in the EEA in line with Regulation (EC) No 726/2004 and Directive 2001/83/EC. The following ICSR types are collected in EVPM: “Spontaneous Report”, “Report from Study” with study type “Individual patient use” and “Other studies”, “Other” and “Not available to sender (unknown)”.
- **EudraVigilance Clinical Trial Module (EVCTM)** dedicated to the collection of ICSRs of Suspected Unexpected Serious Adverse Reactions (SUSARs) in accordance with Directive 2001/20/EC and 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. The following ICSR types are collected in EVCTM: “Report from Study” with study type “Clinical Trials”.

Note: EVPM and EVCTM can be accessed through EVWEB by registered users, which provides a web interface with a set of functionalities to aid the creation, electronic reporting of and access to ICSRs. EVWEB includes the ICSR Export Manager, which permits the download of ICSRs in the internationally agreed format.

- **eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD),** dedicated as reference source for the coding of substances and medicinal products reported in ICSRs based on the information provided by MAHs in line with Article 57(2), second subparagraph of Regulation (EC)No 726/2004.

[16] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

[17] POLICY/0043 European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)

[18] http://eudravigilance.ema.europa.eu

Data analysis and signal detection component

- **EudraVigilance Data Warehouse and Analysis System (EVDAS),** dedicated to support the EU pharmacovigilance safety monitoring activities with the main focus on signal detection and evaluation of ICSRs.

Adrreports.eu portal

- The **portal** allows to search and view data on suspected adverse reactions for authorised medicinal products in the EEA and provides general information to aid the understanding of the reports.

Adequate quality of ICSRs as reported to EudraVigilance is paramount in implementing this Access Policy. In accordance with Article 24(3) of Regulation (EC) No 726/2004, the Agency is operating procedures that ensure the quality and integrity of the information reported in EudraVigilance. This is performed in collaboration either with the MAH or with the Member State that submitted an ICSR to EudraVigilance. This refers in particular to the responsibilities of these stakeholders with EudraVigilance reporting obligations to:

- Adequately document individual cases and follow-up information in accordance with the Commission Implementing Regulation (EU) No 520/2012 and the Good Pharmacovigilance Practices (GVP) module VI[19];
- Apply latest MedDRA coding in in accordance with the Commission Implementing Regulation (EU) No 520/2012 and the MedDRA Term Selection Points to Consider document[20];
- Operate local duplicate detection and management procedures;
- Adhere with the reporting timelines of suspected serious and non-serious adverse reactions;
- Comply with personal data protection requirements as set out in the GDPR, as well as in any national data protection legislation as applicable to the data processing activities of the stakeholder concerned;

and the responsibility of the Agency for the:

- Coding of medicinal product information reported in ICSRs against the standards, formats and terminologies as outlined in Commission Implementing Regulation (EU) No 520/2012;
- Operation of procedures to ensure the quality and integrity of ICSRs reported in EudraVigilance including the detection and management of duplicated individual cases;
- Monitoring of the adherence with reporting timelines of ICSRs;
- Compliance with personal data protection requirements as set out in the EU DPR.

[19] Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products (EMA/873138/2011)
[20] http://www.ich.org/products/meddra.html

5.2. Access to data held in EudraVigilance

5.2.1. Stakeholder Groups

The stakeholders being granted access to EudraVigilance data can be grouped as follows:

- Medicines regulatory authorities in EEA Member States, the European Commission and the Agency (hereafter referred to as Stakeholder Group I)
- Healthcare Professionals and the Public[21] (hereafter referred to as Stakeholder Group II)
- Marketing Authorisation Holders (hereafter referred to as Stakeholder Group III)
- Academia (hereafter referred to as Stakeholder Group IV)
- WHO – Uppsala Monitoring Centre (hereafter referred to as Stakeholder Group V)
- Medicines regulatory authorities in third countries (hereafter referred to as Stakeholder Group VI).

5.2.2. General Principles

Reports of suspected adverse reactions collected in EudraVigilance as derived from legal obligations placed on medicines regulatory authorities and MAHs in EEA Member States. These reports are categorised in different report types (ICH E2B(R3) C.1.3 "Type of Report"). The Agency grants access to EudraVigilance data based on the type of reports, which are further described in Annex A.

Access to ICSR data in EudraVigilance is provided independent of the primary source (i.e. the person who provides the facts about the ICSR), the sender of the report (e.g. a medicines regulatory authority or a MAH) or the country, where the suspected adverse reaction occurred or was reported.

The data elements for ICSRs are defined in the "Implementation Guide for the Electronic Transmission of Individual Case Safety Reports (ICSRs) and E2B(R3) Data Elements and Message Specification" of the ICH E2B Expert Working Group and the corresponding EU Individual Case Safety Report (ICSR) Implementation Guide.

Access is defined based on the stakeholder's interests and needs as well as the requirement to comply with applicable personal data protection legislation. The protection of personal data is a fundamental right of EU citizens. Therefore, the access is further defined in different levels taking into account that due to the often detailed nature of the information not all data elements can be disclosed to avoid a potential re-identification of data subjects.

Annex B lists all 272 ICSR data elements (excl. batch wrapper and message header) and outlines those that can be accessed by each stakeholder group based on the levels defined in Table 1.

It also needs to be recognised that not all data elements of ICSRs are always completed. This means that although access is provided to certain data elements, information may not always be available given the type of the report or the primary source of the information. Moreover, the new ISO ICSR format foresees the use of additional data elements previously not available. This implies that with the implementation of the ISO ICSR standard/ICH E2B(R3) format, information for these data elements

[21] Public in the sense of people in general, rather than being limited to a particular group of people; this can include interest groups, communication media, pharmaceutical companies, academia and others

may not be available for legacy data i.e. ICSRs reported previously to EudraVigilance in the ICH E2B(R2) format.

Table 1. Description of access levels

Access Level	Description
Level 1	• Public subset of ICSR data elements with main focus on • Stakeholder groups II, III, IV, V and VI.
Level 2A	Extended subset of ICSR data elements with main focus on • Stakeholder group III to fulfil their pharmacovigilance obligations. • Stakeholder group IV to directly advance public health and work, which is intended to improve procedures for protecting public health.
Level 2B	Extended subset of ICSR data elements including case narratives with main focus on • Stakeholder group III to validate signals.
Level 2C	Extended subset of ICSR data elements with main focus on • Stakeholder group V and VI thus fostering protection of public health outside the EEA.
Level 3	All ICSR data elements without restrictions with main focus on • Stakeholder group I taking into account their roles and responsibilities to protect public health. • Stakeholder group III to fulfil their pharmacovigilance obligations based on the ICSRs that a MAH has sent to EudraVigilance or on ICSRs resulting from the medical literature monitoring activities performed by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004.

A summary of the number of ICSR data elements accessible in EudraVigilance for each of the six stakeholder groups based on the principles outlined in this Access Policy is provided in Table 3. A detailed description of access to ICSR data held in EudraVigilance for each stakeholder group is provided in chapter 5.2.5.

Further details on the adverse reaction reporting and ICSR management principles are provided in Annex A.

For the purpose of access to ICSR data in EudraVigilance by healthcare professionals and the public, MAHs, academia, WHO-UMC and medicines regulatory authorities in third countries, the information held in the xEVMPD serves as a reference for data coding and data retrieval purposes.

5.2.3. Personal Data Protection

The Agency, medicines regulatory authorities in EEA Member States and in third countries, MAHs, academia as well as WHO-UMC are responsible for:

- Ensuring confidentiality of ICSR data in accordance with the applicable law on personal data protection;
- Protecting personal data in accordance with the applicable law on personal data protection;
- Implementing appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss in accordance with the applicable law on personal data protection.

Personal data shall mean 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 (see Article 3(1) of the EU DPR and Article 4(1) of the GDPR).

For the Agency the provisions set out in the EU DPR apply; for medicines regulatory authorities in EEA Member States, MAHs and academia the requirements set out in the GDPR and (where relevant) in national data protection legislation apply.

The Agency is also operating a procedure for access and rectification. In case the Agency is not able to identify the relevant ICSRs, it will refer to the medicines regulatory authority or the MAH from which the reports likely originate.

5.2.4. Methods of providing access to ICSR data held in EudraVigilance

Access to EudraVigilance data is provided through easy to use query and data retrieval functions based on the EudraVigilance system components described in chapter 5.1. Table 2. provides an overview of the system components applied to provide access to ICSR data for each stakeholder group and outlines the overall format of the data outputs.

Table 2. EudraVigilance system components with ICSR data outputs by stakeholder group

EudraVigilance System Component	Data Outputs
Stakeholder Group I Medicines regulatory authorities in EEA Member States, the European Commission and the Agency	
• EV Gateway for the electronic re-routing of ICSRs to medicines regulatory authorities in EEA Member States based on primary source country for regulatory purposes	• ICSR electronic (XML) format
• EVWEB including ICSR Export Manager	• ICSR electronic (XML) format • ICSR forms
• EVDAS	• e-RMRs and active substance groupings • ICSR line listings • ICSR forms • Other data outputs based on predefined and customisable query and signal detection functionalities
Stakeholder Group II Healthcare Professionals and the Public	
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • ICSR line listings (based on core ICSR data elements) • ICSR forms (for individual case review)
Stakeholder Group III Marketing Authorisation Holders	
• EVWEB including ICSR Export Manager	• ICSRs electronic (XML) format • ICSR forms
• EVDAS	• e-RMRs and active substance groupings • ICSR line listings • ICSR forms
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • ICSR line listings (based on core ICSR data elements)

EudraVigilance System Component	Data Outputs
	• ICSR forms (for individual case review)
Stakeholder Group IV Academia	
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • ICSR line listings (based on core ICSR data elements) • ICSR forms (for individual case review)
• Not applicable	• Ad-hoc preparation of data set by the Agency based on receipt of a research request; data format will depend on research request
Stakeholder Group V WHO UMC	
• Application programming interface (API) between WHO UMC and the Agency	• ICSRs electronic (XML) format
Stakeholder Group VI Medicines regulatory authorities in third countries	
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • ICSR line listings (based on core ICSR data elements) • ICSR forms (for individual case review)
• Not applicable	• Ad-hoc preparation of data set by the Agency following specific request; data format will depend on the nature of the request

Table 3. Overview of number of ICH E2B(R3) ICSR data elements accessible by stakeholder group (excl. batch wrapper and message header)

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Group V & VI
		Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
C.1 Identification of the case safety report	**20**	20	3	18	18	20	16
C.2.r Primary source(s) of information	**15**	15	4	4	4	15	4
C.3 Information on sender of case safety information	**16**	16	3	3	3	16	3
C.4.r Literature reference(s)	**2**	2	1	1	1	2	1
C.5 Study identification	**6**	6	4	5	5	6	5
D. Patient characteristics	**96**	96	4	87	87	96	16
E.i Reaction(s) / event(s)	**21**	21	11	21	21	21	18
F.r Results of tests and procedures relevant to the investigation of the Patient	**13**	13	0	13	13	13	0
G.k Drug(s) information	**76**	76	23	72	72	76	71
H. Narrative case summary and further information	**7**	7	0	4	7	7	0
Grand Total	**272**	**272**	**53**	**228**	**230**	**272**	**134**

5.2.5. Detailed description of access to ICSR data held in EudraVigilance by Stakeholder Group

5.2.5.1. Stakeholder Group I: Medicines Regulatory Authorities in the EEA, the European Commission and the Agency

5.2.5.1.1. Reports of suspected adverse reactions in EVPM

In accordance with Article 24 of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for all ICSR data elements for all medicinal products authorised in the EEA.

For further details refer to Table 4.

Table 4. Access to ICSR data by Medicines Regulatory Authorities in the EEA, the Agency and the European Commission

Stakeholder Group I	Disclosure	Access Authorisation
• Medicines Regulatory Authorities in EEA Member States • Agency • European Commission	• Type of report: – Spontaneous report – Report from study ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 3: – All data elements for ICSRs reported to EVPM (for details refer to Annex B)	Authorised Personnel

5.2.5.1.2. Methods of Access

A description of how access is provided to stakeholder group I including the main data outputs is given in chapter 5.2.4.

5.2.5.1.3. Access Authorisation

Access is granted to authorised personnel of the European Commission, the Agency and Medicines Regulatory Authorities in the EEA. The identification of 'authorised personnel' is based on the EudraVigilance registration process[22]. In Member States, where regional pharmacovigilance centres are

[22] http://eudravigilance.ema.europa.eu/human/HowToRegister.asp

established, the responsible medicines regulatory authority determines the level of access, which should be granted to these centres.

5.2.5.1.4. Personal data protection requirements

The ICSR data access provisions (Level 3) apply without prejudice to the GDPR and the EU DPR. The fundamental right to protection of personal data has to be fully and effectively guaranteed in all pharmacovigilance activities.

More specifically, taking into account the recommendations of the EDPS, stakeholder group I is responsible for ensuring that:

- Information is included on EudraVigilance in their privacy statements on their pharmacovigilance activities[23].
- Confidentiality of ICSRs and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- Appropriate technical and organisational measures are implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance.

5.2.5.2. Group II: Healthcare Professionals and the Public

5.2.5.2.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 24 of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for a defined set of ICSR data elements in compliance with the EU DPR on personal data protection. This applies to spontaneous reports for all medicinal products authorised in the EEA independent of the authorisation procedure. General explanations and guidance on the nature and the interpretation of the accessible data is provided on the adrreports.eu portal.

For further details refer to Table 5.

[23] An information notice for EMA's processing is available on the website www.adrreports.eu

Table 5. Access to EudraVigilance data by healthcare professionals and the public

Stakeholder Group II	Disclosure	Access Authorisation
Healthcare Professionals and the Public	• Type of report: – Spontaneous report • ICSR Level 1: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B)	Not required

5.2.5.2.2. Methods of Access

A description of how access is provided to stakeholder group II including the main data outputs is given in chapter 5.2.4.

5.2.5.2.3. Access Authorisation

No authorisation for accessing the data by means of the adrreports.eu portal is required i.e. all healthcare professionals and the public can access adverse reaction data of interest.

5.2.5.2.4. Personal data protection requirements

Data access and provision is based on a defined ICSR data set (Level 1) in compliance with the EU DPR. A statement on data privacy is included under the section “Background” of the adrreports.eu portal. The Agency is also operating a procedure for access and rectification in line with the aforementioned Regulation.

5.2.5.3. Group III: Marketing Authorisation Holders

5.2.5.3.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 24 of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided to MAHs for a defined set of ICSR data elements in compliance with the EU DPR.

For further details refer to Table 6.

Table 6. Access to EudraVigilance data by Marketing Authorisation Holders

Stakeholder Group III	Disclosure	Access Authorisation
Marketing Authorisation Holders	• Type of report: – Spontaneous reports – Reports from studies	EU Qualified Person Responsible for Pharmacovigilance (EU QPPV) (headquarter level), appointed Deputy and

Stakeholder Group III	Disclosure	Access Authorisation
	▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 1: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B) made available through EVDAS	authorised personnel under the strict responsibility of the EU QPPV.
	• Type of report: – Spontaneous reports – Reports from studies ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 2A: – Extended subset of ICSR data elements (for details refer to Annex B)	EU QPPV (headquarter level), appointed Deputy and authorised personnel under the strict responsibility of the EU QPPV.
	• Type of report: – Spontaneous reports – Reports from studies ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 2B: – Extended subset of ICSR data elements including case narrative (for details refer to Annex B)	EU QPPV (headquarter level) /appointed Deputy and authorised personnel under the strict responsibility of the EU QPPV based on submission of a formal request and the signed confidentiality undertaking for MAHs (see Annex C).
	• Type of report:	EU QPPV (headquarter level)/appointed Deputy and

Stakeholder Group III	Disclosure	Access Authorisation
	– Spontaneous reports – Reports from studies ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 3*: – All data elements for ICSRs that MAH submitted ("Sender-based") to EVPM – Reports originating from the Agency's medical literature monitoring activities pursuant to Article 27 of Regulation (EC) No 726/2004 (for details refer to Annex B)	authorised personnel under the strict responsibility of the EU QPPV.

Roles and responsibilities of MAHs in the context of signal detection and validation and ICSR data access in EudraVigilance are defined in the Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management.[24]

5.2.5.3.2. Methods of access

A description of how access is provided to stakeholder group III including the main data outputs is given in chapter 5.2.4.

5.2.5.3.3. Access Authorisation

Access to ICSR data elements Level 1 and 2A is granted to authorised personnel of a MAH at headquarter level. The identification of authorised personnel under the strict responsibility of the EU QPPV is based on the EudraVigilance registration process. The EU QPPV of the MAH (headquarter level) or their registered Deputy nominates the authorised personnel in line with the EudraVigilance registration process and is responsible for updating the user registration for their organisation accordingly.

ICSR Level 2B access is granted to the EU QPPV/registered Deputy and any other personnel under the strict responsibility of the EU QPPV of a MAH at headquarter level following the receipt of a formal request by the EU QPPV or their registered Deputy in the context of signal management or where a review of ICSR data is warranted in the context of a pharmacovigilance assessment procedure in line

[24] Guideline on good pharmacovigilance practices: Module IX – Signal management (EMA/827661/2011)

with GVP Modules IX and VII[25] and following acceptance of the confidentiality undertaking for MAHs (see Annex C).

5.2.5.3.4. Personal data protection requirements

The access provisions apply without prejudice to applicable Union data protection legislation. The fundamental right to protection of personal data have to be fully and effectively guaranteed in all pharmacovigilance activities. More specifically, taking into account the recommendations of the EDPS, stakeholder group III is responsible for ensuring that:

- Information is included on EudraVigilance in their privacy statements on their pharmacovigilance activities[26].
- Confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- Appropriate technical and organisational measures are implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance.

5.2.5.4. Group IV: Academia

5.2.5.4.1. Reports of suspected adverse reactions in EVPM

In the context of this Access Policy the following definition applies:

'Academia' or 'Academic sector' should be understood as consisting of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations[27].

'**Non-profit organisation' or 'non-profit legal entity'** should be understood as a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members[28].

'Legal entity' should be understood as any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations[29].

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[25] Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report (EMA/816292/2011)

[26] An information notice for EMA's processing is available on the website www.adrreports.eu

[27] MSCA Standard Eligibility Conditions: Extract from the MSCA part of the main Work Programme" of 10 December 2013

[28] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[29] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

'**International European interest organisation'** should be understood as an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe[30].

In accordance with the provisions of Article 24 of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for a defined set of ICSR data elements (Level 1) in compliance with the EU DPR.

Furthermore, an extended ICSR data set (Level 2A) for substances or substance classes for medicinal products authorised in the EEA can be made available to academia by the Agency based on the following principles:

- The Agency supports efforts that aim to directly advance public health and work which is intended to improve procedures for protecting public health.
- The data to be provided should be sufficient to carry out work aimed at achieving either of the objectives named above and should observe EU legislation on protection of personal data.
- A research request should be submitted to the Agency using the form "Send a question to the European Medicines Agency[31]".
  - The research request should address as a minimum the primary research question, the methodology to be used, the way that the results will impact on public health and the name and contact details of the person nominated by the academic institution to safeguard the EudraVigilance data for the research purpose. These details should not exceed 1500 words and should be provided in English. In addition, the request should include a description of a proposed privacy check to be performed by the academic institution prior to any publication with the objective to prevent a release of personal data and the possible re-identification of data subjects (e.g. patients, reporters).
  - Together with the research request, a signed copy of the acceptance of the confidentiality undertaking (see Annex D) for academia must be submitted by the nominated person of the research organisation and all members of the research team. Data may not be transferred to any third party.
- A panel with representatives from the Agency's Pharmacovigilance and Epidemiology Department and the Business Data and Analytics Department will review the research request for the purpose of preparing the ICSR data set required for the research. The data quality will be the best available to the Agency at the time of request. Metadata (i.e. explanations on how to interpret the data e.g. comparisons to baselines) essential for the interpretation of the EudraVigilance data set for which access is provided, will be also made available by the Agency where applicable.
- The Agency will not review the validity or soundness of the research proposal and will apply a standard timescale for response to requests. The Agency may comment on the proposed data privacy check approach in the context of publications related to the research request.

[30] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[31] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp; a template will be made available at the dedicated webpage "Access to EudraVigilance data" of the Agency's corporate website

- The academic researchers should make all possible efforts to publish their research outcome. A copy of any associated articles should be provided to the Agency at least 5 business days ahead of publication. This is for information purposes only.

Table 7. Access to EudraVigilance data by Academia

Stakeholder Group IV	Disclosure	Access Authorisation
Academia	• Type of report: – Spontaneous reports • ICSR Level 1: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B)	Not required.
	• Type of report: – Spontaneous reports – Reports from studies ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 2A: – Extended set of ICSR data elements (for details refer to Annex B)	Nominated person by the academic institution following submission of a research request and signature of the confidentiality undertaking for academia see Annex (D).

5.2.5.4.2. Methods of access

A description of how access is provided to stakeholder group IV including the main data outputs is given in chapter 5.2.4.

5.2.5.4.3. Access Authorisation

No authorisation for accessing the ICSR (Level 1) data set by means of the adrreports.eu portal is required i.e. all academic researchers can access adverse reaction data of interest.

Access to an extended data set (ICSR Level 2A) will be provided by the Agency to a person nominated by the academic institution to safeguard the EudraVigilance data following submission of a research request and the signature of the confidentiality undertaking for academia based on the principles outlined in chapter 5.2.5.4.1.

5.2.5.4.4. Personal data protection requirements

The personal data protection requirements for ICSR level are identical to those outlined in chapter 5.2.5.3.4.

5.2.5.5. Group V: World Health Organisation

5.2.5.5.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 28c of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions occurring in the EEA and reported to EVPM is provided for a defined set of ICSR data elements (Level 1 and Level 2C) in compliance with the EU DPR.

For details refer to Table 8.

Table 8. Access to EudraVigilance data by WHO-UMC

Stakeholder Group V	Disclosure	Access Authorisation
World Health Organisation-Uppsala Monitoring Centre	• Type of report: – Spontaneous reports • ICSR Level 1: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B)	Not required
	• Type of report: – Spontaneous reports – Reports from studies ▪ Individual patient use ▪ Other studies – Other – Not available to sender • ICSR Level 2C: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA. (for details refer to Annex B)	WHO-UMC authorised personnel as per data transfer arrangement between the Agency and WHO-UMC

5.2.5.5.2. Methods of access

A description of how access is provided to stakeholder group V including the main data outputs is given in chapter 5.2.4.

5.2.5.5.3. Access Authorisation

No authorisation for accessing the ICSR data set (Level 1) by means of the adrreports.eu portal is required.

For the access to the extended ICSR data set (Level 2C), the details are further defined in the arrangement between the Agency and WHO-UMC on modalities for making available EU adverse reaction reports to VigiBase and arrangements for the data transfer and use, taking into account the principle of data quality, purpose limitation and adequate safeguards for the protection of personal data ("Data Transfer Arrangement").

5.2.5.5.4. Personal data protection requirements

The personal data protection requirements applicable to WHO-UMC are further defined in the data transfer arrangement.

5.2.5.6. Group VI: Medicines regulatory authorities in third countries

5.2.5.6.1. Reports of suspected adverse reactions in EVPM

Access to individual cases of suspected adverse reactions occurring in the EEA and reported to EVPM is provided for a defined set of ICSR data elements (Level 1 and Level 2C) in compliance with the EU DPR.

For further details refer to Table 9.

Table 9. Access to EudraVigilance data by Medicines Regulatory Authorities in third countries

Stakeholder **Group VI**	Disclosure	Access Authorisation
Medicines Regulatory Authorities in third countries	• Type of report: – Spontaneous reports • ICSR Level 1: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B)	Not required
	• Type of report: – Spontaneous reports – Reports from studies ▪ Individual patient use	Nominated contact of Medicines Regulatory Authority in third country

Stakeholder **Group VI**	Disclosure	Access Authorisation
	▪ Other studies – Other – Not available to sender • ICSR Level 2C: – Subset of ICSR data elements for substances/medicinal products authorised in the EEA (for details refer to Annex B)	

5.2.5.6.2. Methods of access

A description of how access is provided to stakeholder group VI including the main data outputs is given in chapter 5.2.4.

5.2.5.6.3. Access authorisation

Access to the ICSR data set Level 2C is provided where the Agency receives a request from a medicines regulatory authority in a third country e.g. in the context of the evaluation of a safety issue related to a medicine. Access is provided to the nominated contact of the medicines regulatory authority.

5.2.5.6.4. Personal data protection requirements

Transfer of data to medicines regulatory authorities in third countries will in any case comply with applicable data protection legislation.

6. Entry into force of the EudraVigilance Access Policy

This Access Policy will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report the EudraVigilance database has achieved full functionality.

ANNEXES

Annex A - Adverse reaction reporting and ICSR management principles

I. General Adverse Reaction Reporting Principles

Reports of suspected adverse reactions collected in EudraVigilance are derived from legal obligations placed on medicines regulatory authorities and MAHs in the EEA.

In accordance with Article 24 of Regulation (EC) No 726/2004, simplified adverse reaction reporting rules will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report, the EudraVigilance database has achieved full functionality.

This implies the following as regards adverse reaction reporting and EudraVigilance:

- Each Member State shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients.
  - Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions, submit the reports electronically to the EudraVigilance database.
  - Member States shall, within 90 days from the receipt of reports, submit reports of non-serious suspected adverse reactions electronically to the EudraVigilance database.
  - Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the EudraVigilance database.
- Marketing authorisation holders shall access those reports of suspected adverse reactions through the EudraVigilance database.
- Marketing authorisation holders shall record all suspected adverse reactions in the Union or in third countries which are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study.
  - Marketing authorisation holders shall submit electronically to the EudraVigilance database information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
  - Marketing authorisation holders shall submit electronically to the EudraVigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
  - For medicinal products containing the active substances referred to in the list of publications monitored by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004, marketing authorisation holders shall not be required to report to the EudraVigilance database the suspected adverse reactions recorded in the listed medical literature, but they shall monitor all other medical literature and report any suspected adverse reactions.
  - Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall

also collect follow-up information on these reports and submit the updates to the Eudravigilance database.

- The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the World Health Organisation.

II. Individual cases, ICSRs and classification rules

- An **Individual Case** is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products to an individual patient at a particular point of time.
- An **Individual Case Safety Report (ICSR)** provides the most complete information related to an individual case at a certain point of time. An individual case can be associated with one or more ICSRs.
- The **Primary Source** of the information is a person who initially reports the facts provided in the ICSR. This should be distinguished from the sender of the ICSR, though the reporter could also be a sender.
- A **Master Case** refers to a situation where information on the same individual case was reported by different senders, which has led to the creation of duplicates in EudraVigilance and which are subsequently consolidated to one single master case. In EudraVigilance all duplicated ICSRs are associated with a master case, so the initial information can be traced back at all times.
- The **ICSR types** refer to the following categories:
  - Spontaneous report
  - Report from study, further qualified by the differentiation between different types of studies (e.g. clinical trials or others)
  - Other, where it is unclear from a literature report whether or not the case(s) cited are spontaneous observations or whether they arise from a study
  - Not available to sender allowing for the transmission of information by a secondary sender (e.g. regulatory authority) where the initial sender did not specify the type of report
  - Where "Report from study" is indicated, the “Study Type Where Reaction(s)/Event(s) Were Observed”, can be used to distinguish the following:
    - Clinical trials (interventional studies)
    - Individual patient use (e.g. ‘compassionate use’ or ‘named patient basis’)
    - Other studies (e.g. pharmacoepidemiology, pharmacoeconomics, intensive monitoring)

Reports of suspected adverse reactions described in the world-wide literature are not captured as a separate type of report. If a case in the literature arises from spontaneous observations, the type of report is classified as ‘Spontaneous’. If the case arises from a study, the type of report is classified as ‘report from study’. If it is unclear from the literature report whether or not the case(s) cited are spontaneous observations or arise from a study, then it is classified as ‘Other’.

- All ICSRs and individual cases are classified in EudraVigilance depending on their specific characteristics:
  - Initial report
  - Follow-up report
  - Nullification report
  - Amendment report
  - Error report
  - Master report
- ICSRs classified as **'Error Reports'** are excluded from access as they refer to incomplete or erroneous reports. If an ICSR is classified as 'Error Report', the sender is required to correct the ICSR and retransmit it before it will be further processed in EudraVigilance.
- **Individual cases that have been nullified in EudraVigilance** based on the receipt of a nullification report are excluded from data-outputs such as used for signal detection and validation and for publication at the adrreports.eu website. For case administration purpose, nullification reports are nevertheless made available to medicines regulatory authorities and to MAHs for substances, for which they hold a marketing authorisation in the EEA. They are also made available to the WHO-UMC.
- ICH ICSR uses **nullFlavors** based on the HL7 Messaging Standard to categorise exceptions. For further information, refer to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs), E2B(R3) Data Elements and Message Specification Version 5.01, 12 April 2013. Not all nullFlavors are valid for all ICSR data elements.

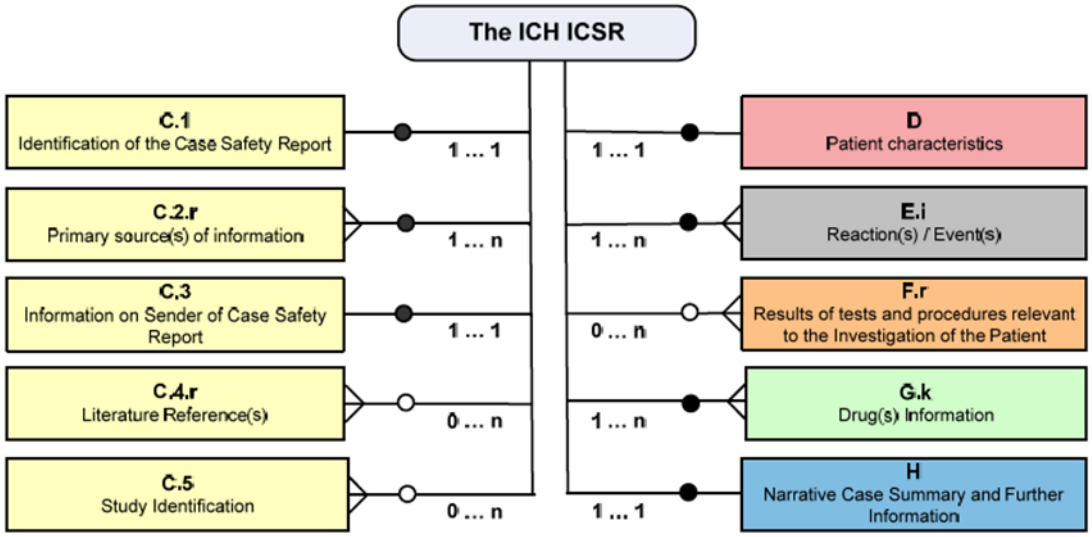
Annex B - ICSR data elements accessible by stakeholder group

This chapter provides a list of all data elements for ICSRs defined in the "Implementation Guide for the Electronic Transmission of Individual Case Safety Reports (ICSRs) and E2B(R3) Data Elements and Message Specification" of the ICH E2B Expert Working Group and the corresponding EU Individual Case Safety Report (ICSR) Implementation Guide. For details refer to Table 10.

It further outlines the access of ICSR data elements provided for each stakeholder group as defined in chapter5.1. 5.2.1.

An overview of the ICH ICSR data structure with the 10 main sections is provided in Figure 1.

Figure 1. ICH ICSR data structure



A summary of the stakeholder groups and their levels of access to ICSR data held in EudraVigilance is provided in Figure 2. and Figure 3.

Figure 2. Access to ICSR data held in EudraVigilance for stakeholder groups I-VI

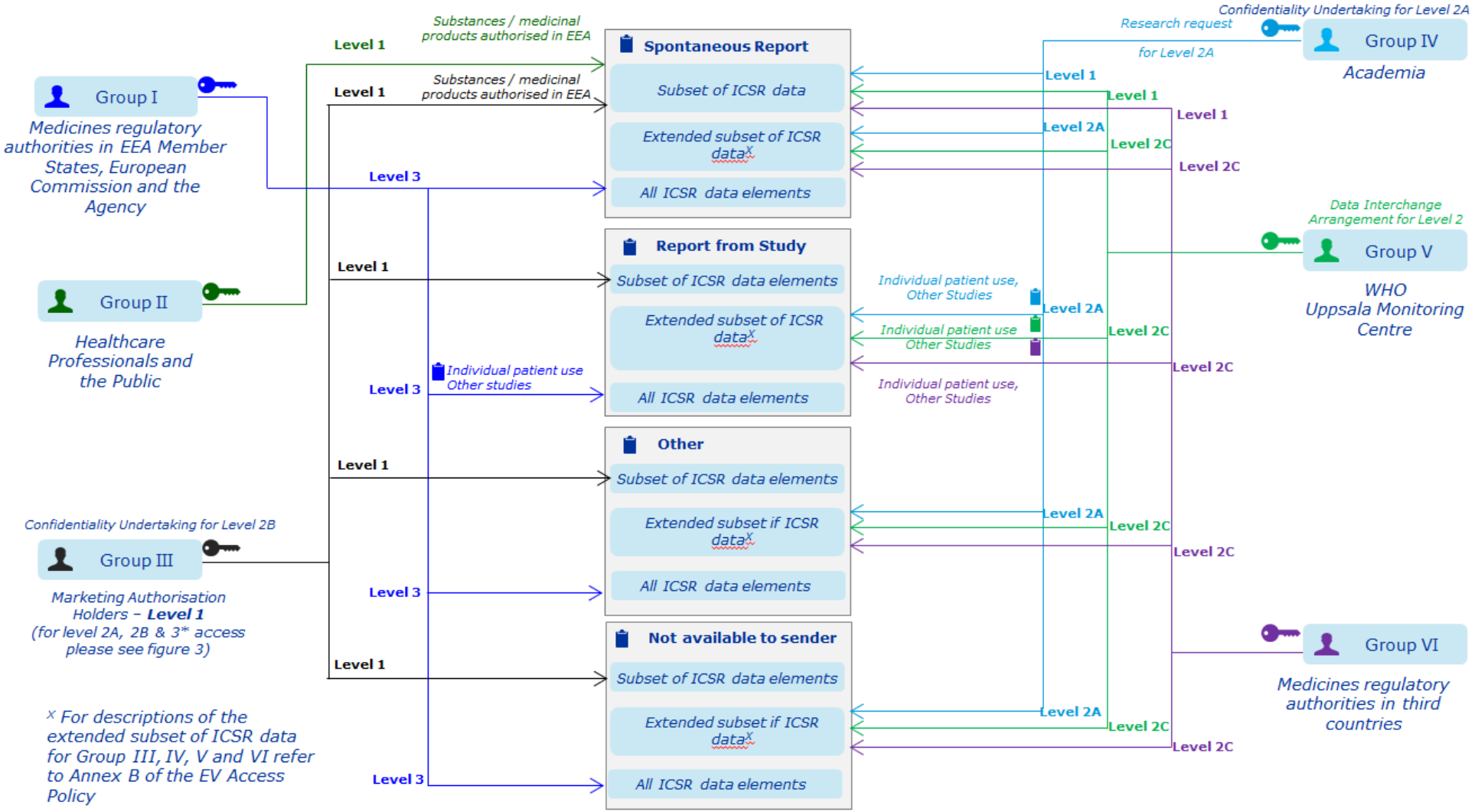


Figure 3. Access to ICSR data held in EudraVigilance for stakeholder group III

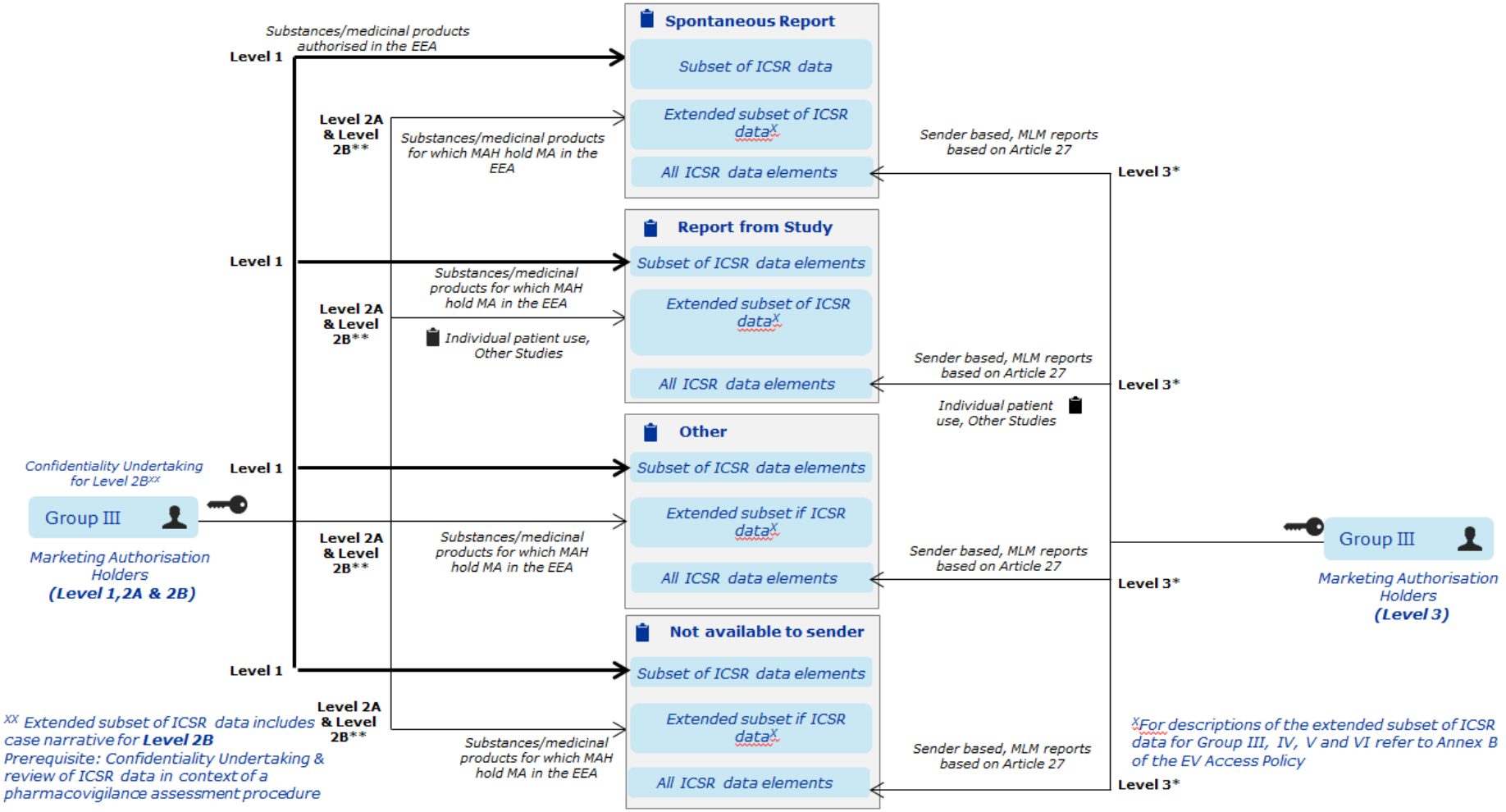


Table 10. Access to ICSR data elements by stakeholder group

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	**N.1 ICH ICSR Transmission Identification (batch wrapper)**							
ICH	N.1.1	Types of Message in batch	Y	N	Y	Y	Y	Y
ICH	N.1.1.CSV	Types of Message in batch code system version	Y	N	Y	Y	Y	Y
ICH	N.1.2	Batch Number	Y	N	N	N	Y	Y
ICH	N.1.3	Batch Sender Identifier	Y	N	N	N	Y	Y
ICH	N.1.4	Batch Receiver Identifier	Y	N	N	N	Y	Y
ICH	N.1.5	Date of Batch Transmission[A]	Y	N	N	N	Y	Y
ICH	**N.2.R ICH ICSR Message Header (message wrapper) (Repeat as necessary)**							
ICH	N.2.r.1	Message Identifier	Y	N	N	N	Y	Y
ICH	N.2.r.2	Message Sender Identifier	Y	N	Y	Y	Y	Y
ICH	N.2.r.3	Message Receiver Identifier	Y	N	N	N	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	N.2.r.4	Date of Message Creation[A]	Y	N	Y	Y	Y	Y
ICH	**C.1 Identification of the Case Safety Report**							
ICH	C.1.1	Sender's (case) Safety Report Unique Identifier	Y	N	Y	Y	Y	Y
ICH	C.1.2	Date of Creation	Y	N	Y	Y	Y	Y
ICH	C.1.3	Type of Report	Y	Y	Y	Y	Y	Y
ICH	C.1.3.CSV	Type of Report Code system version	Y	Y	Y	Y	Y	Y
ICH	C.1.4	Date Report Was First Received from Source	Y	N	Y	Y	Y	Y
ICH	C.1.5	Date of Most Recent Information for This Report	Y	N	Y	Y	Y	Y
ICH	C.1.6.1	Are Additional Documents Available?	Y	N	Y	Y	Y	N
ICH	**C.1.6.1.r Identification of the Case Safety Report**							

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	C.1.6.1.r.1	Documents Held by Sender	Y	N	Y	Y	Y	N
ICH	C.1.6.1.r.2	Included Documents	Y	N	N	N	Y	N
-	-	-	-	-	-	-	-	-
ICH	C.1.7	Does This Case Fulfil the Local Criteria for an Expedited Report?	Y	N	N	N	Y	N
ICH	C.1.8.1	Worldwide Unique Case Identification	Y	Y/N[H]	Y	Y	Y	Y
ICH	C.1.8.2	First Sender of This Case	Y	N	Y	Y	Y	Y
ICH_CSV	C.1.8.2.CSV	First Sender of This Case Code system version	Y	N	Y	Y	Y	Y
ICH	C.1.9.1	Other Case Identifiers in Previous Transmissions	Y	N	Y	Y	Y	Y
ICH	**C.1.9.1.r Source(s) of the Case Identifier(s) (repeat as necessary)**							
ICH	C.1.9.1.r.1	Source(s) of the Case Identifier	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	C.1.9.1.r.2	Case Identifier(s)	Y	N	Y	Y	Y	Y
ICH	**C.1.10.r Identification Number of the Report Which Is Linked to This Report (repeat as necessary)**							
ICH	C.1.10.r	Identification Number of the Report Which Is Linked to This Report	Y	N	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	C.1.11.1	Report Nullification / Amendment	Y	N	Y	Y	Y	Y
ICH_CSV	C.1.11.1.CSV	Report Nullification / Amendment Code system version	Y	N	Y	Y	Y	Y
ICH	C.1.11.2	Reason for Nullification / Amendment	Y	N	Y	Y	Y	Y
ICH	**C.2.r Primary Source(s) of Information (repeat as necessary)**							

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
ICH	C.2.r.1.1	Reporter's Title	Y	N	N	N	Y	N
ICH	C.2.r.1.2	Reporter's Given Name	Y	N	N	N	Y	N
ICH	C.2.r.1.3	Reporter's Middle Name	Y	N	N	N	Y	N
ICH	C.2.r.1.4	Reporter's Family Name	Y	N	N	N	Y	N
ICH	C.2.r.2.1	Reporter's Organisation	Y	N	N	N	Y	N
ICH	C.2.r.2.2	Reporter's Department	Y	N	N	N	Y	N
ICH	C.2.r.2.3	Reporter's Street	Y	N	N	N	Y	N
ICH	C.2.r.2.4	Reporter's City	Y	N	N	N	Y	N
ICH	C.2.r.2.5	Reporter's State or Province	Y	N	N	N	Y	N
ICH	C.2.r.2.6	Reporter's Postcode	Y	N	N	N	Y	N
ICH	C.2.r.2.7	Reporter's Telephone	Y	N	N	N	Y	N
ICH	C.2.r.3	Reporter's Country Code	Y	Y[B]	Y	Y	Y	Y
ICH	C.2.r.4	Qualification	Y	Y	Y	Y	Y	Y
ICH_CSV	C.2.r.4.CSV	Qualification code system	Y	Y	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
		version						
ICH	C.2.r.5	Primary Source for Regulatory Purposes	Y	Y[B]	Y	Y	Y	Y
ICH	**C.3 Information on Sender of Case Safety Report**							
ICH	C.3.1	Sender Type	Y	Y	Y	Y	Y	Y
ICH_CSV	C.3.1.CSV	Sender Type code system version	Y	Y	Y	Y	Y	Y
ICH	C.3.2	Sender's organisation	Y	Y[I]	Y	Y	Y	Y
ICH	C.3.3.1	Sender's Department	Y	N	N	N	Y	N
ICH	C.3.3.2	Sender's Title	Y	N	N	N	Y	N
ICH	C.3.3.3	Sender's Given Name	Y	N	N	N	Y	N
ICH	C.3.3.4	Sender's Middle Name	Y	N	N	N	Y	N
ICH	C.3.3.5	Sender's Family Name	Y	N	N	N	Y	N
ICH	C.3.4.1	Sender's Street Address	Y	N	N	N	Y	N
ICH	C.3.4.2	Sender's City	Y	N	N	N	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	C.3.4.3	Sender's State or Province	Y	N	N	N	Y	N
ICH	C.3.4.4	Sender's Postcode	Y	N	N	N	Y	N
ICH	C.3.4.5	Sender's Country Code	Y	N	N	N	Y	N
ICH	C.3.4.6	Sender's Telephone	Y	N	N	N	Y	N
ICH	C.3.4.7	Sender's Fax	Y	N	N	N	Y	N
ICH	C.3.4.8	Sender's E-mail Address	Y	N	N	N	Y	N
ICH	**C.4.r Literature Reference(s) (repeat as necessary)**							
ICH	C.4.r.1	Literature Reference(s)	Y	Y	Y	Y	Y	Y
ICH	C.4.r.2	Included Documents	Y	N	N	N	Y	N
ICH	**C.5 Study Identification**							
ICH	**C.5.1.r Study Registration (repeat as necessary)**							
ICH	C.5.1.r.1	Study Registration Number	Y	Y	Y	Y	Y	Y
ICH	C.5.1.r.2	Study Registration country	Y	N	N	N	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
-	-	-	-	-	-	-	-	-
ICH	C.5.2	Study Name	Y	Y	Y	Y	Y	Y
ICH	C.5.3	Sponsor Study Number	Y	N	Y	Y	Y	Y
ICH	C.5.4	Study Type Where Reaction(s) / Event(s) Were Observed	Y	Y	Y	Y	Y	Y
ICH_CSV	C.5.4.CSV	Study Type Where Reaction(s) / Event(s) Were Observed code system version	Y	Y	Y	Y	Y	Y
ICH	**D. Patient Characteristics**							
ICH	D.1	Patient (name or initials)	Y	N	N	N	Y	N
ICH	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)	Y	N	N	N	Y	N
ICH	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist	Y	N	N	N	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
		Record Number)						
ICH	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	Y	N	N	N	Y	N
ICH	D.1.1.4	Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)	Y	N	N	N	Y	N
ICH	**D.2 Age Information** [C,D]							
ICH	D.2.1	Date of Birth	Y	N	N	N	Y	N
ICH	D.2.2a	Age at Time of Onset of Reaction / Event (number)	Y	N[D]	Y	Y	Y	Y
ICH	D.2.2b	Age at Time of Onset of Reaction / Event (unit)	Y	N[D]	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
ICH	D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (number)	Y	N	Y	Y	Y	N
ICH	D.2.2.1b	Gestation Period When Reaction/Event Was Observed in the Foetus (unit)	Y	N	Y	Y	Y	N
ICH	D.2.3	Patient Age Group (as per reporter)	Y	Y	Y	Y	Y	Y
ICH_CSV	D.2.3.CSV	Patient Age Group (as per reporter) code system version	Y	Y	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	D.3	Body Weight (kg)	Y	N	Y	Y	Y	N
ICH	D.4	Height (cm)	Y	N	Y	Y	Y	N
ICH	D.5	Sex	Y	Y	Y	Y	Y	Y
ICH	D.6	Last Menstrual Period Date	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	**D.7.1.r Structured Information on Relevant Medical History (repeat as necessary)**							
ICH	D.7.1.r.1a	MedDRA Version for Medical History	Y	N	Y	Y	Y	N
ICH	D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code[E])	Y	N	Y	Y	Y	N
ICH	D.7.1.r.2	Start Date	Y	N	Y	Y	Y	N
ICH	D.7.1.r.3	Continuing	Y	N	Y	Y	Y	N
ICH	D.7.1.r.4	End Date	Y	N	Y	Y	Y	N
ICH	D.7.1.r.5	Comments	Y	N	Y	Y	Y	N
ICH	D.7.1.r.6	Family History	Y	N	Y	Y	Y	N
-	-	-	-	-	-	-	-	-
ICH	D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	D.7.3	Concomitant Therapies	Y	N	Y	Y	Y	N
ICH	**D.8.r Relevant Past Drug History[F] (repeat as necessary)**							
ICH	D.8.r.1	Name of Drug as Reported	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.1	Name part - Invented name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.2	Name part - Scientific name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.3	Name part - Trademark name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.4	Name part - Strength name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.5	Name part - Form name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.6	Name part - Container name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.7	Name part - Device name	Y	N	Y	Y	Y	N
EU	D.8.r.1.EU.8	Name part - Intended use name	Y	N	Y	Y	Y	N
ICH	D.8.r.2a	MPID Version Date/Number	Y	N	Y	Y	Y	N
ICH	D.8.r.2b	Medicinal Product Identifier	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
		(MPID)						
ICH	D.8.r.3a	PhPID Version Date/Number	Y	N	Y	Y	Y	N
ICH	D.8.r.3b	Pharmaceutical Product Identifier (PhPID)	Y	N	Y	Y	Y	N
EU	**D.8.r.EU.r Substance / Specified Substance Identifier and Strength[F] (repeat as necessary)**							
EU	D.8.r.EU.r.1	Substance / Specified Substance Name	Y	N	Y	Y	Y	N
EU	D.8.r.EU.r.2a	Substance/Specified Substance TermID Version Date/Number	Y	N	Y	Y	Y	N
EU	D.8.r.EU.r.2b	Substance/Specified Substance TermID	Y	N	Y	Y	Y	N
EU	D.8.r.EU.r.3a	Strength (number)	Y	N	Y	Y	Y	N
EU	D.8.r.EU.r.3b	Strength (unit)	Y	N	Y	Y	Y	N
-	-	-	-	-	-	-	-	-

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	D.8.r.4	Start Date	Y	N	Y	Y	Y	N
ICH	D.8.r.5	End Date	Y	N	Y	Y	Y	N
ICH	D.8.r.6a	MedDRA Version for Indication	Y	N	Y	Y	Y	N
ICH	D.8.r.6b	Indication (MedDRA code[E])	Y	N	Y	Y	Y	N
ICH	D.8.r.7a	MedDRA Version for Reaction	Y	N	Y	Y	Y	N
ICH	D.8.r.7b	Reaction (MedDRA code[E])	Y	N	Y	Y	Y	N
-	-	-	-	-	-	-	-	-
ICH	D.9.1	Date of Death	Y	N	Y	Y	Y	Y
ICH	**D.9.2.r Reported Cause(s) of Death (repeat as necessary)**							
ICH	D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	Y	N	Y	Y	Y	Y
ICH	D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code[E])	Y	N	Y	Y	Y	Y
ICH	D.9.2.r.2	Reported Cause(s) of Death (free text)	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
-	-	-	-	-	-	-	-	-
ICH	D.9.3	Was Autopsy Done?	Y	N	Y	Y	Y	Y
ICH	D.**9.4.r Autopsy-determined Cause(s) of Death (repeat as necessary)**							
ICH	D.9.4.r.1a	MedDRA Version for Autopsy-determined Cause(s) of Death	Y	N	Y	Y	Y	Y
ICH	D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code[E])	Y	N	Y	Y	Y	Y
ICH	D.9.4.r.2	Autopsy-determined Cause(s) of Death (free text)	Y	N	Y	Y	Y	N
ICH	**D.10 For a Parent-Child / Foetus Report, Information Concerning The Parent [C,D]**							
ICH	D.10.1	Parent Identification	Y	N	N	N	Y	N
ICH	D.10.2.1	Date of Birth of Parent	Y	N	N	N	Y	N
ICH	D.10.2.2a	Age of Parent (number)	Y	N[D]	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	D.10.2.2b	Age of Parent (unit)	Y	N[D]	Y	Y	Y	Y
ICH	D.10.3	Last Menstrual Period Date of Parent	Y	N	Y	Y	Y	Y
ICH	D.10.4	Body Weight (kg) of Parent	Y	N	Y	Y	Y	N
ICH	D.10.5	Height (cm) of Parent	Y	N	Y	Y	Y	N
ICH	D.10.6	Sex of Parent	Y	Y	Y	Y	Y	Y
ICH	**D.10.7 Relevant Medical History and Concurrent Conditions of Parent**							
ICH	**D.10.7.1.r Structured Information of Parent (repeat as necessary)**							
ICH	D.10.7.1.r.1a	MedDRA Version for Medical History	Y	N	Y	Y	Y	N
ICH	D.10.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code[E])	Y	N	Y	Y	Y	N
ICH	D.10.7.1.r.2	Start Date	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	D.10.7.1.r.3	Continuing	Y	N	Y	Y	Y	N
ICH	D.10.7.1.r.4	End Date	Y	N	Y	Y	Y	N
ICH	D.10.7.1.r.5	Comments	Y	N	Y	Y	Y	N
-	-	-	-	-	-	-	-	-
ICH	D.10.7.2	Text for Relevant Medical History and Concurrent Conditions of Parent	Y	N	N	N	Y	N
ICH	**D.10.8.r Relevant Past Drug History of Parent [F] (repeat as necessary)**							
ICH	D.10.8.r.1	Name of Drug as Reported	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.1	Name part - Invented name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.2	Name part - Scientific name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.3	Name part - Trademark name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.4	Name part - Strength name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.5	Name part - Form name	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
EU	D.10.8.r.1.EU.6	Name part - Container name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.7	Name part - Device name	Y	N	Y	Y	Y	N
EU	D.10.8.r.1.EU.8	Name part - Intended use name	Y	N	Y	Y	Y	N
ICH	D.10.8.r.2a	MPID Version Date/Number	Y	N	Y	Y	Y	N
ICH	D.10.8.r.2b	Medicinal Product Identifier (MPID)	Y	N	Y	Y	Y	N
ICH	D.10.8.r.3a	PhPID Version Date/Number	Y	N	Y	Y	Y	N
ICH	D.10.8.r.3b	Pharmaceutical Product Identifier (PhPID)	Y	N	Y	Y	Y	N
EU	**D.10.8.r.EU.r Substance / Specified Substance Identifier and Strength[F] (repeat as necessary)**							
EU	D.10.8.r.EU.r.1	Substance / Specified Substance Name	Y	N	Y	Y	Y	N
EU	D.10.8.r.EU.r.2a	Substance/Specified Substance TermID Version Date/Number	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
EU	D.10.8.r.EU.r.2b	Substance/Specified Substance TermID	Y	N	Y	Y	Y	N
EU	D.10.8.r.EU.r.3a	Strength (number)	Y	N	Y	Y	Y	N
EU	D.10.8.r.EU.r.3b	Strength (unit)	Y	N	Y	Y	Y	N
-	-	-	-	-	-	-	-	-
ICH	D.10.8.r.4	Start Date	Y	N	Y	Y	Y	N
ICH	D.10.8.r.5	End Date	Y	N	Y	Y	Y	N
ICH	D.10.8.r.6a	MedDRA Version for Indication	Y	N	Y	Y	Y	N
ICH	D.10.8.r.6b	Indication (MedDRA code[E])	Y	N	Y	Y	Y	N
ICH	D.10.8.r.7a	MedDRA Version for Reaction	Y	N	Y	Y	Y	N
ICH	D.10.8.r.7b	Reactions (MedDRA code[E])	Y	N	Y	Y	Y	N
ICH	**E.i Reaction(s)/Event(s) (repeat as necessary)**							
ICH	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native Language	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	Y	N	Y	Y	Y	N
ICH	E.i.1.2	Reaction / Event as Reported by the Primary Source for Translation	Y	N	Y	Y	Y	N
ICH	E.i.2.1a	MedDRA Version for Reaction / Event	Y	N	Y	Y	Y	Y
ICH	E.i.2.1b	Reaction / Event (MedDRA code[E])	Y	Y	Y	Y	Y	Y
ICH	E.i.3.1	Term Highlighted by the Reporter	Y	N	Y	Y	Y	Y
ICH_CSV	E.i.3.1.CSV	Term Highlighted by the Reporter code system version	Y	N	Y	Y	Y	Y
ICH	E.i.3.2a	Results in Death	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2b	Life Threatening	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2c	Caused / Prolonged	Y	Y	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
		Hospitalisation						
ICH	E.i.3.2d	Disabling / Incapacitating	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2e	Congenital Anomaly / Birth Defect	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2f	Other Medically Important Condition	Y	Y	Y	Y	Y	Y
ICH	E.i.4	Date of Start of Reaction / Event	Y	N	Y	Y	Y	Y
ICH	E.i.5	Date of End of Reaction / Event	Y	N	Y	Y	Y	Y
ICH	E.i.6a	Duration of Reaction / Event (number)	Y	Y	Y	Y	Y	Y
ICH	E.i.6b	Duration of Reaction / Event (unit)	Y	Y	Y	Y	Y	Y
ICH	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	Y	Y	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH_CSV	E.i.7.CSV	Outcome of Reaction / Event at the Time of Last Observation code system version	Y	Y	Y	Y	Y	Y
ICH	E.i.8	Medical Confirmation by Healthcare Professional	Y	N	Y	Y	Y	Y
ICH	E.i.9	Identification of the Country Where the Reaction / Event Occurred	Y	N	Y	Y	Y	Y
ICH	**F.r Results of Tests and Procedures Relevant to the Investigation of the Patient (repeat as necessary)**							
ICH	F.r.1	Test Date	Y	N	Y	Y	Y	N
ICH	F.r.2.1	Test Name (free text)	Y	N	Y	Y	Y	N
ICH	F.r.2.2a	MedDRA Version for Test Name	Y	N	Y	Y	Y	N
ICH	F.r.2.2b	Test Name (MedDRA code[E])	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	F.r.3.1	Test Result (code)	Y	N	Y	Y	Y	N
ICH_CSV	F.r.3.1.CSV	Test Result (code) code system version	Y	N	Y	Y	Y	N
ICH	F.r.3.2	Test Result (value / qualifier)	Y	N	Y	Y	Y	N
ICH	F.r.3.3	Test Result (unit)	Y	N	Y	Y	Y	N
ICH	F.r.3.4	Result Unstructured Data (free text)	Y	N	Y	Y	Y	N
ICH	F.r.4	Normal Low Value	Y	N	Y	Y	Y	N
ICH	F.r.5	Normal High Value	Y	N	Y	Y	Y	N
ICH	F.r.6	Comments (free text)	Y	N	Y	Y	Y	N
ICH	F.r.7	More Information Available	Y	N	Y	Y	Y	N
ICH	**G.k Drug(s) Information[F] (repeat as necessary)**							
ICH	G.k.1	Characterisation of Drug Role	Y	Y	Y	Y	Y	Y
ICH_CSV	G.k.1.CSV	Characterisation of Drug Role code system version	Y	Y	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	G.k.2.1.1a	MPID Version Date / Number	Y	N	Y	Y	Y	Y
ICH	G.k.2.1.1b	Medicinal Product Identifier (MPID)	Y	N	Y	Y	Y	Y
ICH	G.k.2.1.2a	PhPID Version Date/Number	Y	Y	Y	Y	Y	Y
ICH	G.k.2.1.2b	Pharmaceutical Product Identifier (PhPID)	Y	Y	Y	Y	Y	Y
ICH	G.k.2.2	Medicinal Product Name as Reported by the Primary Source[F]	Y	Y/N[G]	Y	Y	Y	Y
EU	G.k.2.2.EU.1	Name part - Invented name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.2	Name part - Scientific name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.3	Name part - Trademark name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.4	Name part - Strength name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.5	Name part - Form name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.6	Name part - Container name	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
EU	G.k.2.2.EU.7	Name part - Device name	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.8	Name part - Intended use name	Y	N	Y	Y	Y	Y
EU	**G.k.2.2.EU.9 Device component (repeat as necessary)**							
EU	G.k.2.2.EU.9.r.1	Device Component name (free text)	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.9.r.2	Device Component TermID version Date/Number	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.9.r.3	Device Component TermID	Y	N	Y	Y	Y	Y
EU	G.k.2.2.EU.9.r.4	Device serial number	Y	N	Y	Y	Y	Y
ICH	**G.k.2.3 Substance / Specified Substance Identifier and Strength (repeat as necessary)**							
ICH	G.k.2.3.r.1	Substance / Specified Substance Name[F]	Y	Y	Y	Y	Y	Y
ICH	G.k.2.3.r.2a	Substance/Specified Substance TermID Version	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
		Date/Number						
ICH	G.k.2.3.r.2b	Substance/Specified Substance TermID	Y	Y	Y	Y	Y	Y
ICH	G.k.2.3.r.3a	Strength (number)	Y	N	Y	Y	Y	Y
ICH	G.k.2.3.r.3b	Strength (unit)	Y	N	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	G.k.2.4	Identification of the Country Where the Drug Was Obtained	Y	N	Y	Y	Y	Y
ICH	G.k.2.5	Investigational Product Blinded	Y	N	N	N	Y	N
ICH	G.k.3.1	Authorisation / Application Number	Y	N	N	N	Y	Y
ICH	G.k.3.2	Country of Authorisation / Application	Y	N	N	N	Y	N
ICH	G.k.3.3	Name of Holder / Applicant	Y	N	N	N	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	**G.k.4.r Dosage and Relevant Information (repeat as necessary)**							
ICH	G.k.4.r.1a	Dose (number)	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.1b	Dose (unit)	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.2	Number of Units in the Interval	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.3	Definition of the Time Interval Unit	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.4	Date and Time of Start of Drug	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.5	Date and Time of Last Administration	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.6a	Duration of Drug Administration (number)	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.6b	Duration of Drug Administration (unit)	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.7	Batch / Lot Number	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
ICH	G.k.4.r.8	Dosage Text	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.9.1	Pharmaceutical Dose Form (free text)	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date/Number	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.10.1	Route of Administration (free text)	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.10.2a	Route of Administration TermID Version Date / Number	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.10.2b	Route of Administration TermID	Y	Y	Y	Y	Y	Y
ICH	G.k.4.r.11.1	Parent Route of Administration (free text)	Y	N	Y	Y	Y	Y
ICH	G.k.4.r.11.2a	Parent Route of Administration TermID	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
		Version Date / Number						
ICH	G.k.4.r.11.2b	Parent Route of Administration TermID	Y	Y	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	G.k.5a	Cumulative Dose to First Reaction (number)	Y	N	Y	Y	Y	Y
ICH	G.k.5b	Cumulative Dose to First Reaction (unit)	Y	N	Y	Y	Y	Y
ICH	G.k.6a	Gestation Period at Time of Exposure (number)	Y	N	Y	Y	Y	Y
ICH	G.k.6b	Gestation Period at Time of Exposure (unit)	Y	N	Y	Y	Y	Y
ICH	**G.k.7.r Indication for Use in Case (repeat as necessary)**							
ICH	G.k.7.r.1	Indication as Reported by the Primary Source	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	G.k.7.r.2a	MedDRA Version for Indication	Y	N	Y	Y	Y	Y
ICH	G.k.7.r.2b	Indication (MedDRA code[E])	Y	Y	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	G.k.8	Action(s) Taken with Drug	Y	Y	Y	Y	Y	Y
ICH_CSV	G.k.8.CSV	Action(s) Taken with Drug code system version	Y	Y	Y	Y	Y	Y
ICH	**G.k.9.i Drug-reaction(s) / Event(s) Matrix (repeat as necessary)**							
ICH	G.k.9.i.1	Reaction(s) / Event(s) Assessed	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.2.r.1	Source of Assessment	Y	N	Y	Y	Y	Y
EU	G.k.9.i.2.r.1.EU.1	EU Source of Assessment	Y	N	Y	Y	Y	Y
EU_CSV	G.k.9.i.2.r.1.EU.1.CSV	EU Source of Assessment code system version	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.2.r.2	Method of Assessment	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
EU	G.k.9.i.2.r.2.EU.1	EU Method of Assessment	Y	N	Y	Y	Y	Y
EU_CSV	G.k.9.i.2.r.2.EU.1.CSV	EU Method of Assessment code system version	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.2.r.3	Result of Assessment	Y	N	Y	Y	Y	Y
EU	G.k.9.i.2.r.3.EU.1	EU Result of Assessment	Y	N	Y	Y	Y	Y
EU_CSV	G.k.9.i.2.r.3.EU.1.CSV	EU Result of Assessment code system version	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	Y	N	Y	Y	Y	Y

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	ICSR ICH E2B(R3) Element Reference	DATA ELEMENT NAME	Level 3	Level 1	Level 2A	Level 2B	Level 3*	Level 2C
ICH	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	Y	N	Y	Y	Y	Y
ICH	G.k.9.i.4	Did Reaction Recur on Re-administration?	Y	Y	Y	Y	Y	Y
ICH_CSV	G.k.9.i.4.CSV	Did Reaction Recur on Re-administration? Code system version	Y	Y	Y	Y	Y	Y
-	-	-	-	-	-	-	-	-
ICH	G.k.10.r	Additional Information on Drug (coded) (repeat as necessary)	Y	Y	Y	Y	Y	Y
ICH_CSV	G.k.10.r.CSV	Additional Information on Drug (coded) (repeat as necessary) code system version	Y	Y	Y	Y	Y	Y
ICH	G.k.11	Additional Information on Drug (free text)	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	**H Narrative Case Summary and Further Information**							
ICH	H.1	Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information	Y	N	N	Y	Y	N
ICH	H.2	Reporter's Comments	Y	N	Y	Y	Y	N
ICH	**H.3.r Sender's Diagnosis (repeat as necessary)**							
ICH	H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	Y	N	Y	Y	Y	N
ICH	H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code[E])	Y	N	Y	Y	Y	N

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Groups V & VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 2A**	**Level 2B**	**Level 3***	**Level 2C**
ICH	H.4	Sender's Comments	Y	N	Y	Y	Y	N
ICH	**H.5.r Case Summary and Reporter's Comments in Native Language (repeat as necessary)**							
ICH	H.5.r.1a	Case Summary and Reporter's Comments Text	Y	N	N	Y	Y	N
ICH	H.5.r.1b	Case Summary and Reporter's Comments Language	Y	N	N	Y	Y	N

Table 11. Legend

Reference	Explanation
*	ICSRs that a MAH has sent to EudraVigilance or ICSRs resulting from the medical literature monitoring activities performed by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004
A	Displayed as EV Gateway Receipt Date
B	Country code displayed as EEA or Non-EEA.
C	Age is calculated at the time of onset of reaction (if available). If several reactions/events are reported, the age at the time of the first reaction/event is used. For foetal reaction(s)/event(s) D.2.2.1a/b "Gestation period when reaction/event was observed in the fetus" is used (if available). A validation is performed to ensure that all dates of onset of reactions –in case of multiple reactions- fall within a 12 months period. If the dates are beyond a 12 months onset period, age is not calculated.
D	Age and patient age group are mapped to a defined age grouping scheme applied in EudraVigilance
E	MedDRA code is displayed as MedDRA term
F	Recoded against the information on medicinal products held in the XEVMPD where applicable; where the reported information cannot be coded against the XEVMPD, the information is displayed in un-coded format
G	Yes for centrally authorised medicinal products/ No for non-centrally authorised medicinal products
H	Displayed at the *adrreports.eu portal* with the value of the "EudraVigilance Local Report Number". The "EudraVigilance Local Report Number" is assigned by the EudraVigilance system and is an alphanumeric code without semantic information. Displayed in *EVWEB and EVDAS (secure systems with access control) with the value of the* "Worldwide Unique Case Identification Number" to facilitate the identification and management of potential duplicates by stakeholder group III in their own pharmacovigilance databases.
I	Displayed at the adrreports.eu portal as "EEA Regulator" when the Sender Type=2 "Regulatory Authority" or Sender Type = 4 "Regional Pharmacovigilance Centre".

Annex C - Confidentiality Undertaking for marketing authorisation holders

Introduction

This Confidentiality Undertaking is aimed principally at ensuring the protection of personal data. It governs the access and use by marketing authorisation holders in the European Economic Area (EEA) of the ICSR data set Level 2B as defined in chapter 5.2.5.3. of the European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (Doc. Ref. EMA/759287/2009 Revision 4) ("Policy"). By signing the Confidentiality Undertaking, access to ICSR data set Level 2B will be granted to the marketing authorisation holder by the Agency.

Access to the ICSR data set Level 2B under the policy

The marketing authorisation holder acknowledges that the ICSR data set level 2B will be made available in electronic format. Before being granted access to the ICSR data set level 2B, the marketing authorisation holder shall provide the EMA with:

- A confirmation that either:
  - The initial signal management steps as outlined in the Good Pharmacovigilance Practice Guide Module IX "Signal Management" have been performed, including a reference to the corresponding e-RMR if applicable;
  - A review of ICSR data is warranted in the context of a pharmacovigilance assessment procedure such as the PSUR as outlined in GVP Module VII or when required by the PRAC in a referral or signal assessment procedure;
- Elements concerning the identity of the marketing authorisation holder (Organisation ID Headquarter level, name and contact details in accordance with the EudraVigilance Registration details);
- A copy of the Confidentiality Undertaking signed by the EU QPPV and where different, by the Deputy appointed by the EU QPPV or any other personnel, under the strict responsibility of the EU QPPV, who is registered with EudraVigilance and holds a valid user ID and password and obtains access to the ICSR data set Level 2B, which includes a case narrative.

Confidentiality Undertaking

As a condition of my access to the EudraVigilance database, for the purpose of ensuring the protection of personal data therein, I agree to the following terms:

- I agree at all times to treat as confidential all information related to the ICSR data set Level 2B and to use it for the purpose of signal management as outlined in GVP Module IX or in the context of a pharmacovigilance assessment procedure such as the Periodic Safety Update Report as outlined in GVP Module VII or when required by the PRAC in a referral or signal assessment procedure according to the conditions set in this Undertaking and in compliance with applicable data protection legislation. In particular, I agree not to seek to identify, profile, contact or target the data subjects from the ICSR data set Level 2B.
- I agree not to transfer or dispose of the ICSR data set Level 2B for which access is provided under the condition of this Confidentiality Undertaking to any third party, where there are no legal obligations for the marketing authorisation holder to do so. I shall not permit any third party to access, study, analyse, refer to or otherwise use the data or permit any party to reproduce any ICSR data.
- I agree to access and use only the minimal amount of personal data that is necessary for the performance of my pharmacovigilance activities pursuant to the applicable laws and I agree to acknowledge that the source of the data is the EudraVigilance database.
- I shall ensure that any personal information is pseudonymised when there is a legal requirement for the marketing authorisation holder to report suspected adverse reactions for the medicinal products for which they hold a marketing authorisation in the EEA to a medicines regulatory authority in a third country. To that end, I ensure that the personal data reported can no longer be attributed to a specific data subject.
- I agree to maintain adequate technical and security measures to prevent unauthorised or unlawful access, disclosure, dissemination, alteration, destruction, accidental loss or copying of the ICSR data set Level 2B, in accordance with applicable data protection legislation, and to immediately notify the Agency of a breach of security leading to any thereof.
- I acknowledge that this Undertaking will be in effect from the date of my signature and that the terms of this Undertaking will apply to any secondary analysis of the ICSR data set Level 2B I perform using the Eudravigilance data.
- I understand that compliance with this Confidentiality Undertaking is a condition of my access to the Eudravigilance database and that failure to comply may result in immediate termination of my right of access and use of the data.

I have read, understood and I agree to comply with the terms stated above at all times.

Name: _____ Title: _____

Signature: _____ Date: _____

Annex D - Confidentiality Undertaking for Academia

This Confidentiality Undertaking is aimed principally at ensuring the protection of personal data. It governs the access and use by academia of the ICSR data set Level 2A as defined in chapter 5.2.5.4. of the European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (Doc. Ref. EMA/759287/2009 Revision 4) ("Policy"). By signing the Confidentiality Undertaking, ICSR access to the data set Level 2A will be granted to the academic institution by the Agency.

Access to the ICSR data set Level 2A under the policy

The academic institution acknowledges that the ICSR data set level 2A will be made available in the most suitable electronic format based on the research request submitted to the EMA. Before being granted access to the ICSR data set level 2A, the academic institution shall provide the EMA with:

- An e-mail address;
- A place of address in the European Union. In the event that the academic institution does not have a place of address in the European Union and wishes to avail itself of the services of a third party resident or domiciled in the European Union, such third party shall be considered a representative of the academic institution for the purpose of the Confidentiality Undertaking and shall comply with all the terms hereof;
- Elements concerning the identity of the person nominated by the academic institution requesting access to the ICSR data set Level 2A under the policy (i.e. name, date of birth, passport or ID card number, expiry date of the document; the affiliation and position within the organisation);
- A signed copy of the Confidentiality Undertaking (signed by the person nominated by the academic institution and requesting access to the ICSR data set Level 2A under the Policy and all members of the research team).

Confidentiality Undertaking

As a condition of my access to the EudraVigilance database, for the purpose of ensuring the protection of personal data therein, I agree to the following terms:

- I agree at all times to treat as confidential all information related to the ICSR data set Level 2A and to use it according to the conditions set in this Undertaking and in compliance with applicable data protection legislation. In particular, I agree not to seek to identify, profile, contact or target the data subjects from the ICSR data set Level 2A.
- I agree not to transfer or dispose of the ICSR data set Level 2A for which access is provided under the condition of this Confidentiality Undertaking to any third party. I shall not permit any third party to access, study, analyse, refer to or otherwise use the data or permit any party to reproduce any ICSR data.
- I agree to access and use only the minimal amount of personal data that is necessary for the performance of my research activities and I acknowledge that the source of the data is the EudraVigilance database.
- I agree to ensure that any publications or reports based on the use of EudraVigilance database do not contain personal information. Personal information mean any recorded information that could, either by itself or in combination with other information, be used to link or associate the information to a particular individual.
- I agree to maintain adequate technical and security measures to prevent unauthorised or unlawful access, disclosure, dissemination, alteration, destruction, accidental loss or copying of the ICSR data set Level 2A in accordance with applicable data protection legislation and to immediately notify the Agency of a breach of security leading to any thereof.
- I agree to use the data only for the purposes of bona fide research activities and for no other purpose. I agree to provide a copy of any article using this ICSR data to the Agency for information at least 5 business days before its publication. I acknowledge that this Undertaking will be in effect from the date of my signature and that the terms of this Undertaking will apply to any subsequent research projects I perform using EudraVigilance data.
- I understand that compliance with this Confidentiality Undertaking is a condition of my access to the EudraVigilance database and that failure to comply may result in immediate termination of my right to access or possess the data.

I have read, understood and I agree to comply with the terms stated above at all times. (the person nominated by the academic institution and requesting access to the ICSR data set Level 2A under the Policy and all members of the research team must sign this form)

Name: _____ Title: _____

Signature: _____ Date: _____

Annex E - Acronyms

CHMP	Committee for Medicinal Products for Human Use
CMD-h	Coordination Group for Mutual Recognition and Decentralised Procedures – Human
EDPS	European Data Protection Supervisor
EEA	European Economic Area
EMA	European Medicines Agency
EO	European Ombudsman
EVCTM	EudraVigilance Clinical Trial Module
EVDAS	EudraVigilance Data Warehouse and Analysis System
EV-EWG	EudraVigilance Expert Working Group
EVPM	EudraVigilance Post-Authorisation Module
EU	European Union
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary
eRMR	Electronic Reaction Monitoring Report
GVP	Good Pharmacovigilance Practices
HCPWP	Healthcare Professionals' Working Party
HMA	Heads of Medicines Agencies
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
PCWP	Patients' and Consumers' Working Party
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
QPPV	Qualified Person for Pharmacovigilance
WHO	World Health Organisation
WHO-UMC	World Health Organisation Uppsala Monitoring Centre