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European Medicines Agency

## Electronic reporting to EudraVigilance

### List of reference documents

Document title	Description
<a href="#">Announcement of the EMA Management Board – Confirmation of the mandatory use of the ISO Individual Case Report standard based on ICH E2B(R3) modalities and related ISO standard terminology</a> (EMA/561671/2019)	The announcement of the EMA's Management Board confirming that the use of EDQM codes for Route of Administration and Dosage Forms and the ICH E2B(R3) message format became mandatory for the Individual Case Safety Reports (ICSR) / Suspected Unexpected Serious Adverse Reactions (SUSAR) submission to EudraVigilance since 30 June 2022.
<a href="#">European Union individual case safety report (ICSR) implementation guide</a> (EMA/51938/2013)	This guidance describes the EU-specific requirements to generate a valid ICSR safety and acknowledgment message in the international format EN ISO ICSR 27953-2:2011 in accordance with ICH E2B(R3) guidance and should be read in conjunction with the ICH E2B(R3) implementation guide and related materials published on the ICH website.
<a href="#">ICH Implementation guide package</a> (the PDF document is included as item #1 of the <a href="#">Step 4 ICH IG Package</a> )	A set of documents including the ICH ICSR implementation guide, backwards and forwards compatibility recommendations and element mapping.
<a href="#">ICH E2B(R3) Questions and answers</a> (this PDF document is published by ICH in this <a href="#">webpage</a> )	A question-and-answer document relevant for technical E2B questions.
<a href="#">Mandatory use of ISO ICSR/ICH E2B(R3) and EDQM terminology for Dosage Forms (DF) and Routes of Administration (RoA) Change management plan</a> (EMA/580321/2021)	This change management document describes the activities performed by the EMA to support the stakeholders during the implementation of the ICH E2B(R3) message format and the EDQM codes for Route of Administration and Dosage Forms.

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<a href="#">User Guide: Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message</a> (the PDF document is included as item #10 of the <a href="#">Step 4 ICH IG Package</a> )	This User Guide published by ICH should be used in conjunction with the ICH E2B(R3) Implementation Guide (IG) and associated documents for electronic exchange of Individual Case Safety Reports (ICSRs). Specifically, this document applies only to the terms maintained by the European Directorate for the Quality of Medicines & HealthCare (EDQM) that relate to Pharmaceutical Dose Forms (DF) and Routes of Administration (RoA) in E2B(R3) format messages.
<a href="#">EudraVigilance: Obtaining EDQM terms from SPOR</a> (EMA/580322/2021)	This guide provides additional details on how to use the SPOR RMS system.
<a href="#">EU R2 Dosages to EDQM mapping</a>	This list provides a mapping of the previously published EU R2 dosage forms.
<a href="#">UCUM units for E2B(R3)</a>	The list of valid UCUM units that can be used in the EU for E2B(R3).
<a href="#">EU E2B(R3) code lists</a>	The list of codes for EU-specific data fields.
<a href="#">EU reference instances (EDQM Revision)</a>	ICH reference instances (amended to include EU-specific data fields).
<a href="#">EU example instances</a>	Additional example instances to be used for testing E2B(R3) transmissions to EudraVigilance.
<a href="#">The launch of the new EudraVigilance System Questions and answers (Q&amp;A) – from stakeholders</a> (EMA/679813/2018)	This document compiles and addresses stakeholder questions related to the launch of the new EudraVigilance System, which went live on 22 November 2017. It includes queries received via the Agency’s service desk and during EMA’s technical and pharmacovigilance support webinars.
<a href="#">EudraVigilance stakeholder change management plan</a> (EMA/325783/2016)	This document details the changes taking place in the EudraVigilance system and to the process of reporting ICSRs and SUSARs.
<a href="#">Regulation (EU) No 536/2014</a>	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.
<a href="#">Clinical Trials Regulation (EU) No 536/2014 – Questions &amp; Answers</a>	Questions and Answers Document on Regulation (EU) 536/2014 (the Clinical Trials Regulation).
<a href="#">Recommendations on the use of Auxiliary Medicinal Products in Clinical Trials written and endorsed by the Clinical Trials Coordination and Advisory Group (CTAG)</a>	A document endorsed by the Clinical Trials Coordination and Advisory Group that aims at clarifying the use of Auxiliary Medicinal Products (AxMPs) – formerly known as Non-Investigational Medicinal Products (NIMPs) – in Clinical Trials.
<a href="#">Regulation No 726/2004</a>	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
<a href="#">Directive 2001/83/EC</a>	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.

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<a href="#">Commission Implementing Regulation No 520/2012</a>	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.
<a href="#">EMA EudraVigilance Access policy</a> (EMA/759287/2009)	This policy outlines the data elements for and the principles of providing access to reports of suspected adverse reactions (ICSRs) in EudraVigilance as regards medicines regulatory authorities and marketing authorisation holders (MAHs) in the EEA, healthcare professionals, patients and consumers/public as well as academia.
<a href="#">European Medicines Agency's Data Protection Notice for EudraVigilance Human (EV)</a> (EMA/381993/2024)	This Data protection notice explains the most essential details of the processing of personal data in the context of the operation of EudraVigilance Human.
<a href="#">Guideline on good pharmacovigilance practices (GVP) Annex I - Definitions</a> (EMA/876333/2011)	Guidance document that contains a comprehensive glossary of important terms and definitions applicable to the Guidelines on Good Pharmacovigilance Practices (GVPs).
<a href="#">Guideline on good pharmacovigilance practices: Module VI – Management and reporting of adverse reactions to medicinal products</a> (EMA/873138/2011)	Addresses the legal requirements detailed in Title IX of Directive 2001/83/EC and chapter 3 of Regulation (EC) No 726/2004 as regards the collection, data management and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use authorised in the European Union (EU).
<a href="#">Guideline on good pharmacovigilance practices (GVP) Module VI Addendum I – Duplicate management of suspected adverse reaction reports</a> (EMA/405655/2016)	Addresses the process for the management of duplicates in the organisations databases.
<a href="#">Guideline on good pharmacovigilance practices (GVP) Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance</a> (EMA/178902/2025)	This addendum provides supplementary guidance to Section VI.C.6.2.2.10 on data protection laws in GVP Module VI, thus forming an integral part of the existing GVP VI guidance; it outlines the specific data elements that must be masked or omitted when submitting ICSRs and SUSARs to the EudraVigilance database and specifies the data elements necessary to fulfil pharmacovigilance and safety monitoring obligations as defined in EU pharmaceutical legislation.
<a href="#">Guideline on good pharmacovigilance practices (GVP): Module IX – Signal management</a> (EMA/827661/2011)	Provides general guidance and requirements on scientific and quality aspects of signal management, describe roles, responsibilities and procedural aspects in the setting of the EU regulatory network and describes methodological aspects of signal detection from spontaneous reports of suspected adverse reactions.

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<a href="#">Guideline on good pharmacovigilance practices (GVP) Module IX Addendum I – Methodological aspects of signal detection from spontaneous reports of suspected adverse reactions</a> (EMA/209012/2015)	This Addendum lists some of the methodological aspects that should be considered in detecting potential signals.
<a href="#">Considerations on the international transfer of personal (health) data in ICSRs/SUSARs originating in the EU</a> (Training Module EV-M8)	This EudraVigilance training module provides stakeholders who have reporting requirements in third countries with an overview of the core GDPR principles (such as data pseudonymisation) whilst also analysing the legal interplay between pharmacovigilance requirements and GDPR and provides the main considerations for addressing the international health data transfers under adequacy decisions or safeguards.
<a href="#">EudraVigilance: how to register</a>	An EMA webpage that details the registration process with the Agency.
<a href="#">EMA EudraVigilance Registration Manual</a> (EMA/13454/2020)	A manual part of the official documentation prepared by the EMA to support the registration of organisations and users in EudraVigilance.
<a href="#">New Organisation First User EU QPPV/RP or Change of EU QPPV/RP</a> (EMA/503895/2018)	This document describes the actions required by MAHs, Commercial and Non-commercial Sponsors of Clinical Trials, and National Competent Authorities (NCAs) for registering or changing their EU Qualified Person for Pharmacovigilance (EU QPPV) / Responsible Person (RP), as applicable.
<a href="#">EudraVigilance registration documents</a> (EMA/503894/2018)	This document summarises the pre-requisites and the required documents in order for MAHs, Commercial and Non-commercial Sponsors of Clinical Trials and National Competent Authorities (NCAs) to register with EMA, including for the assignment or reassignment of the role of EU Qualified Person for Pharmacovigilance (EU QPPV) / Responsible Person (RP).
<a href="#">EudraVigilance: electronic reporting</a>	An EMA webpage that details the electronic reporting of ICSRs / SUSARs to EudraVigilance, including the steps required for preparing for the electronic exchange of safety reports, including <a href="#">EV Quality Assurance Testing (QAT)</a> (for organisations who wish to become Gateway Traders or use the EVPOST function) and <a href="#">what to do in case of system failure</a> .
<a href="#">Reporting safety information on clinical trials</a>	An EMA webpage that provides an overview of the reporting requirements for Sponsors of Clinical Trials
<a href="#">EudraVigilance - EVWEB User Manual</a> (EMA/501718/2018)	A manual is part of the official documentation prepared by the EMA to support the use of the EudraVigilance Web reporting tool (EVWEB).

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<a href="#">Recording by marketing authorisation holders of information on suspected adverse reactions held in EudraVigilance – Note for clarification</a> (EMA/396720/2018)	<p>The purpose of this note for clarification is to address the recording (download) by MAHs of ICSRs held in EudraVigilance. This document aims to provide MAHs with clear guidance and legal certainty about their pharmacovigilance obligations in the EEA in the context of the pharmaceutical legislation for medicinal products for human use so they can adapt their processes and procedures as necessary, and inspections can be conducted in a consistent manner.</p>
<a href="#">Medical literature monitoring</a>	<p>An EMA webpage that details the Medical Literature Monitoring (MLM) service offered by the Agency to MAHs.</p>
<a href="#">Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency – Questions and Answers</a> (EMA/848710/2016)	<p>This Questions and Answers (Q&amp;A) document addresses a set of frequently asked questions from marketing authorisation holders regarding the monitoring of medical literature (MLM) and entry of adverse reaction reports into EudraVigilance by the Agency, in line with Article 27 of Regulation (EC) 726/2014.</p>
<a href="#">Compliance notifications explanation and Q&amp;A – Background to the compliance calculations &amp; anticipated questions from stakeholders</a> (EMA/362031/2025)	<p>A document outlining the Agency’s process for monitoring compliance with reporting timelines – established in pharmaceutical legislation – for ICSRs and SUSARs submitted to EudraVigilance by stakeholders. It details the legal basis, monitoring frequency, the reports and notifications provided to stakeholders, how the compliance is calculated, and includes Frequently Asked Questions.</p>
<a href="#">EudraVigilance support guide</a> (EMA/434681/2023)	<p>A guidance document on the query support options to stakeholders offered by the EMA on EudraVigilance- and Pharmacovigilance-related queries.</p>