NEXTROVE REGULATORY BULLETIN
Staying up to date with the latest regulatory news
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ICH harmonised guideline post-approval safety data: definitions and standards for management and reporting of individual case safety reports E2D(R1)

The ICH E2D (R1) guideline provides guidance on definitions and standards for post-approval individual case safety reporting, as well as good case management practices. It has been finalized in September 2025.

- Several critical elements for pharmacovigilance have been reconfirmed and further clarified.
- Organized Data Collection Systems (ODCS) have been further broken down into PSP, MR, Digital sources.
- Several regulators are actively integrating the ICH E2D(R1) framework into their national legislation.

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ICH Information Paper Regarding Alignment with ICH E2D(R1) Guideline

This Information Paper explains the alignment of ICH E2B(R3) specifications with the revised ICH E2D guideline (referred to as ICH E2D(R1)). This includes updates to two existing ICH E2B(R3) data elements: “C.1.3 Type of Report” and “C.5.4 Study Type Where Reaction(s) / Event(s) Were Observed”. ICH Code List has been updated to accommodate the new values.

Of note:

- The new values for data element “C.5.4 Study Type Where Reaction(s) / Event(s) Were Observed” should be used prospectively.
- ICSRs that have already been submitted to regulatory authorities do not need to be re submitted with a new value.
- However, when submitting a follow-up ICSR or an amendment report, the new values should be used as appropriate.
- The new values should be used as appropriate for newly submitted ICSRs, not just for newly introduced solicited data sources
- Regional implementation for the implementation timelines for accepting the new values for data element “C.5.4 Study Type Where Reaction(s) / Event(s) Were Observed” and additional regional considerations must be monitored
- When a region has not yet implemented the new values for data element “C.5.4 Study Type Where Reaction(s) / Event(s) Were Observed”, the value ‘3 = Other studies should be used for ICSRs originating from patient support programs, market research programs or from organized data collection systems with source data from digital platforms

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EMA

EU implementation strategy of ICH E2D(R1) Guideline - Post-approval safety data: Definitions and standards for management and reporting of individual case safety reports

The purpose of this document is to provide instructions on the practical implementation of the ICH E2D(R1) Guideline - Post-approval safety data: definitions and standards for management and reporting of individual case safety reports (EMA/CHMP/ICH/59123/2024) in the European Union (EU)

The revision of the ICH E2D guideline aims to clarify the management of safety data derived from solicited sources such as social media, market research programs, patient support programs, and others.
The revised Guideline ICH E2D(R1) has been adopted by the ICH Management committee and by the CHMP in September 2025 and it will come officially into effect in the EU 6 months later, on 18 March, 2026.
The revision of the Good Pharmacovigilance Practice (GVP) Module VI will be initiated to integrate the updated ICH E2D(R1) Guideline. In the interim, the guidance and definitions set out in the revised guideline should be applied in accordance with this EU implementation strategy document.
To allow MAHs to update their processes accordingly, an additional 6-month transition period is permitted up to 18 September, 2026. After this date, the definitions and guidance provided in the ICH E2D(R1) Guideline will become applicable.
The new definition introduced in the ICH E2D(R1) Guideline should be implemented by MAHs no later than 18 September, 2026 for all new programs.

Major impact:

- Each new MAH ODCS activity not conducted according to a protocol should have the ICH E2D(R1) documentation in place no later than 18 September, 2026 describing at least the:
    1. Objectives of the ODCS activity;
    2. Source(s) of the data;
    3. Dataset that the MAH will collect or receive and review in order to meet the objectives of the activity detailed under item 1, including the look-back period and/or duration of the data collection;
    4. Method the MAH will use to review the dataset to meet the objective of the activity;
    5. Process for collection and management of any AEs/ADRs or other observations that may be identified.

The documentation should be maintained with oversight by the Qualified Person responsible for Pharmacovigilance (QPPV) and made available to the national competent authorities and the Agency upon request.

- Each ongoing MAH ODCS activity not conducted according to a protocol should have the ICH E2D(R1) documentation in place no later than 18 September, 2026 describing at least the:
    1. Objectives of the ODCS activity;
    2. Source(s) of the data;
    3. Process for collection and management of any AEs/ADRs or other observations that may be identified.

The documentation should be maintained with oversight by the QPPV and made available to the national competent authorities and the Agency upon request.

- ADR from ODCS should be considered solicited, excluding MAH activities that only allow one-way interactions such as delivery of a product to a patient's home, or provision of vouchers or coupons, and ADRs from such programs should be managed as spontaneous reports.

- The value 3 = Other studies (e.g., pharmacoepidemiology, pharmacoeconomics, intensive monitoring)' should continue to be used in data element C.5.4 'Study Type Where Reaction(s) / Event(s) Were Observed' for ICSRs originating from PSPs, until the new values are implemented in EudraVigilance at a later stage

- For ADRs arising from MAH activities that only allow one-way interactions, data element C.1.3 'Type of report' should be populated with the value 1= Spontaneous report.

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US FDA

E2D(R1) Postapproval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports Guidance for Industry

US FDA published Final Guidance for Industry on March, 2026 Final Guidance for Industry for E2D(R1) to fully align definitions, reporting standard
The US FDA implementation of ICH E2D(R1) introduces standardized global expectations for post-approval safety data management. The updated guidance overhauls how Marketing Authorization Holders (MAHs) collect, process, and report adverse events from emerging data sources like social media, patient support programs (PSPs), and digital platforms.

In particular:

- ODCS is now clearly defined. Structured activities such as PSPs, MRs, registries, and certain digital monitoring initiatives fall explicitly within the ODCS concept. This affects case classification (e.g., solicited vs spontaneous), documentation, and reporting workflows.
- Digital platforms under MAH responsibility require active screening.
- Clarification for reporting obligations for observations that aren't typically classified as standard AEs or adverse drug reactions (ADRs). This applies explicitly to instances of lack of efficacy, overdose, abuse, misuse, medication errors, occupational exposure, and off-label use
- Stronger governance expectations for PSPs & MRs
- Clear documentation of program set-up
- Defined roles and responsibilities
- Contractual safety reporting clauses with vendors
- Demonstrable oversight and quality control

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Other Regions:

SWISSMEDIC

National implementation in Switzerland closely coordinates with the regional rollout timelines and strategies established by the EMA

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HEALTH CANADA

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UK

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 came into force on 28 April, 2026.

The new requirements apply to all clinical trials of investigational medicinal products (CTIMPs) whether they were submitted before or from 28 April, 2026.

The sponsor of a clinical trial approved before this date may elect to have the trial temporarily continue in compliance with the previous legislation's safety reporting requirements until the first annual safety report is submitted.

Among the major changes the most impactful as for pharmacovigilance are:

- New definition for non-investigational medicinal product: A non-investigational medicinal product is a medicinal product that is used in a clinical trial, as described in the protocol, but not as an investigational medicinal product
- From 28 April, 2026, SUSARs and annual safety reports for all CTIMPs should only be reported to the MHRA. If any ethical issues are identified by the MHRA when they receive these reports, they will liaise with the REC directly.
- From 28 April, 2026, the period a sponsor must give written notice to the REC and MHRA for Urgent Safety Measures (USMs) has been extended from 3 to 7 days.

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Use of AI for GXP inspection responses: setting standards without stifling innovation

This blog specifically relates to submissions to the MHRA Compliance Teams following GxP inspections.

The MHRA has identified examples of information relating to inspection activity submitted to Compliance Teams which have been generated by Artificial Intelligence. This blog describes current thinking in relation to the use of AI when generating information to support inspections.

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EUROPE

Sponsor handbook Clinical Trial Information System (CTIS) user guidance on the sponsor's workspace

Version 6.3 of Sponsor handbook Clinical Trial Information System (CTIS) user guidance on the sponsor's workspace was published on 26 June, 2026 by EMA.

It provides clinical trial sponsors with the operational guidance to create and submit clinical trial information to the member states of the European Union/European Economic Area (EU/EEA) through CTIS.

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SINGAPORE

Version 6 of the Post-Marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products (CTGTP)

HSA released Version 6 of the Post-Marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products (CTGTP).
Major updates of version 6 guidance:

- Criteria for submission of serious adverse events, with distinction between spontaneous and solicited reports
- Added examples to define identifiable patient
- Types of adverse events which are not subject to reporting requirements
- Criteria for submission of adverse events arising from literature
- eCTD added as an alternative platform for submission of dossier information for therapeutic products
- Criteria for submission of lack of efficacy reports
- RMPs and PBER detailed requirements
- Action taken from HSA reference drug regulatory agencies: Australia Therapeutic Goods Administration (TGA), European Medicines Agency (EMA), Health Canada, Swissmedic, UK Medicines and Healthcare Products Regulatory Agency (MHRA), and US Food and Drug Administration (FDA).

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AUSTRALIA

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products - Guidance for Industry

On 24 May, 2026 the Therapeutic Goods Administration (TGA) adopted the following guidance: Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products - Guidance for Industry.

The guidance is a US FDA guidance and includes references to US legislation, the requirements contained in the referenced US legislation are not applicable to the evaluation of medicines by the TGA.

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USA

Post- approval Pregnancy Safety Studies Guidance for Industry

On May, 2026 US FDA issued the Post-approval Pregnancy Safety Studies Guidance for Industry with recommendations on different methodologies that can be used in the post -approval setting to study the safety of drugs and biological products when used during pregnancy.

Pregnant patients were historically excluded from clinical studies to protect fetuses from potentially harmful exposures. However, this exclusion results in a shift of risk to the postmarketing setting where there may be widespread use.

The purpose of the guidance is to provide sponsors and investigators with recommendations on how to design investigations to assess the safety outcomes of pregnancies in women who are exposed to FDA regulated drug and biological products during pregnancy in the postmarketing setting.

The guidelines describe several methods that should be considered when collecting pregnancy safety data, pregnancy registries, and complementary studies that evaluate real-world data and descriptive studies that rely on reports from individual cases.

The goal is to generate information that can be included in drug labeling to help healthcare providers and patients make informed decisions.

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SAUDI ARABIA

Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations III: Advanced Therapy Medicinal Products

The Saudi Food & Drug Authority (SFDA) has released Version 1.0 of the Guideline on Good Pharmacovigilance Practices: Product or Population Specific Considerations III: Advanced Therapy Medicinal Products (ATMPs).

Date of Issue: 12 April, 2026
Date of Implementation: 12 April, 2027

This guideline provides dedicated guidance for MAHs on pharmacovigilance activities for ATMPs (gene therapy, somatic cell therapy, and tissue-engineered products). It covers critical areas including:

- Risk Management Plans tailored to ATMP-specific risks (tumorigenicity, immunogenicity, vector transmission, germline risks, etc.)
- Long-term safety & efficacy follow-up studies
- Signal management, adverse reaction reporting, and PSUR requirements
- Risk minimization measures, including controlled access programs, educational materials, and patient alert cards
- Methodological considerations for post-authorization studies

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SOUTH AFRICA

Updated Guideline for Industry E-Reporting Regulations 2025

Originally published in February, 2026, South Africa's Health Products Regulatory Authority (SAHPRA) published the first issue of the Guideline for Industry E-Reporting on 17 August, 2026.

This Guideline outlines the process for stakeholders to report electronically, from registration for use of the web-based tool through acknowledgements, and nullification of reports. The comprehensive guide is available for download to begin submissions on SAHPRA's website.

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Questions/Clarification on the Updated Guideline for Industry E-Reporting

On 27 July, 2026, South Africa's Health Products Regulatory Authority (SAHPRA) issued a communication to Industry on the e-Reporting VigiFlow Platform, setting meeting for those submitting marketed and clinical adverse events (AEs) or serious adverse events (SAEs) to ask questions for clarification when utilizing the web-based e-Reporting tool. The meeting was held on August 4, 2026, but enquiries can still be made as follows:

Pharmacovigilance-related issues: Contact Ms. Victoria Sekiti at Victoria.Sekiti@sahpra.org.za and CC pvqueries@sahpra.org.za

Clinical trials-related issues: Contact Ms. Dominicha Thosago at Dominicha.Thosago@sahpra.org.za and CC ctcsaes@sahpra.org.za

Call for Interest – Pilot SAE Reporting via E-Reporting

On 27 July, 2026, SAHPRA issues a communication to stakeholders for volunteers to be part of the pilot project for electronic reporting of SAEs via the VigiFlow Module.

By participating in this program, sponsors, applicants, investigators, and HCRs would be able to report SAEs directly to SAHPRA's national database via uploading an E2B R3 (XML file), replacing the hard copy CIOMS and emailed E2B report submissions.

To participate in the pilot, you can complete the application and requirements per the communication found in Sahpraza SharePoint.

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