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2026 SPECIAL
PHARMACOVIGILANCE,
RISK MINIMIZATION
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PHARMACOVIGILANCE SOLUTIONS

SUMMARY

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THALIDOMIDE: THE SCANDAL THAT CHANGED PHARMACOVIGILANCE FOREVER

TODAY, WE TAKE DRUG SAFETY FOR GRANTED. BUT THIS CERTAINTY CAME AT A TREMENDOUS COST. BETWEEN THE 1950S AND 1960S, A DRUG MARKETED AS COMPLETELY SAFE, FOREVER CHANGED THE HISTORY OF PHARMACOVIGILANCE, LEADING TO ONE OF THE WORST PHARMACEUTICAL DISASTERS OF THE 20TH CENTURY: THALIDOMIDE. PRESCRIBED FOR ANXIETY, INSOMNIA, AND MORNING SICKNESS DURING PREGNANCY, THALIDOMIDE WAS CONSIDERED A BREAKTHROUGH MEDICATION. HOWEVER, ITS MECHANISM OF ACTION TURNED OUT TO BE DEVASTATING: BY INTERFERING WITH FETAL DEVELOPMENT, IT CAUSED SEVERE BIRTH DEFECTS, INCLUDING PHOCOMELIA, A CONDITION IN WHICH LIMBS ARE SHORTENED OR ABSENT.

WHAT IS THALIDOMIDE?

Thalidomide is an active substance with sedative and immunomodulatory properties, developed and marketed in the 1950s by the German pharmaceutical company Chemie Grünenthal. Initially, it was used as an active compound in medications for treating anxiety and insomnia. Unlike other sedatives of the time, it appeared to have an excellent safety profile: it did not cause addiction like barbiturates, showed no obvious signs of toxicity in adults, and was promoted as a “safe-for-all” drug—to the point that, in some countries, it was even available without a prescription. Its widespread use took off when it was found to be effective in treating morning sickness during pregnancy. It seemed like the perfect drug: effective, well-tolerated, and free of noticeable side effects. But the reality was far different.

WHY WAS THALIDOMIDE CONSIDERED SAFE?

At the time, there were no standardized protocols to assess the effects of drugs in humans. Clinical trials were often conducted without strict regulations, failing to consider long-term effects, and there were no clear guidelines for testing drugs on vulnerable populations, such as pregnant women or children. Additionally, teratogenicity testing (evaluating the potential harm to fetal development) was not mandatory, as it was wrongly assumed that the placenta would protect the fetus from chemical substances. For these reasons, Thalidomide was tested on animals without assessing its impact on fetal development, and human clinical trials were conducted on a limited number of healthy volunteers. In some cases, it was even tested on psychiatric patients and prisoners, without any long-term evaluation or consideration of its use during pregnancy. Since no immediate risks emerged from the studies, the manufacturer declared that Thalidomide was “virtually non-toxic.” It was subsequently marketed in 46 countries, spreading rapidly in Germany, the United Kingdom, Australia, Canada, Brazil, and Japan, where it quickly became popular as a sedative and anti-nausea drug.

WHY DID THALIDOMIDE TURN INTO A GLOBAL TRAGEDY?

Unfortunately, Thalidomide was not only considered safe based on incomplete testing, but its mechanism of action was also poorly understood. While its sedative and anti-inflammatory properties were well known, scientists were unaware that it inhibited the formation of new blood vessels (angiogenesis), a process crucial for proper fetal development. Additionally, it damaged neural crest cells, which are essential for the development of limbs, facial structures, and internal organs. The consequences were catastrophic: thousands of babies were born with severe limb deformities, including phocomelia (shortened limbs) or amelia (complete absence of limbs). In other cases, infants suffered from organ malformations or died due to spontaneous abortion. No one had anticipated that a drug harmless to adults could have such a devastating impact on fetuses.

ONE REPORT CAN MAKE THE DIFFERENCE

In 1961, Australian gynecologist William McBride began noticing a disturbing trend. Before 1956, phocomelia was an extremely rare condition, occurring in only 1 in 100,000 newborns. However, between the late 1950s and early 1960s, in countries where Thalidomide was widely used, the incidence skyrocketed to 1 in 2,000 births. McBride suspected a link between the drug and the birth defects. Concerned by his findings, he wrote a letter to The Lancet, one of the world's most prestigious medical journals, warning about the potential dangers.

At the same time, German pediatrician Widukind Lenz conducted a detailed epidemiological study, which confirmed the correlation between Thalidomide and neonatal malformations. In November 1961, he presented his findings at a pediatrics conference in Düsseldorf, increasing pressure on health authorities.

Their warning was crucial. The scientific community acted swiftly, and in December 1961, Thalidomide was withdrawn from the market. This event marked the beginning of modern pharmacovigilance: for the first time, a doctor's report led to the global withdrawal of a drug. The case demonstrated a critical lesson: every report can make a difference saving thousands of lives.

THE THALIDOMIDE CASE AND THE PHARMACOVIGILANCE BIRTH

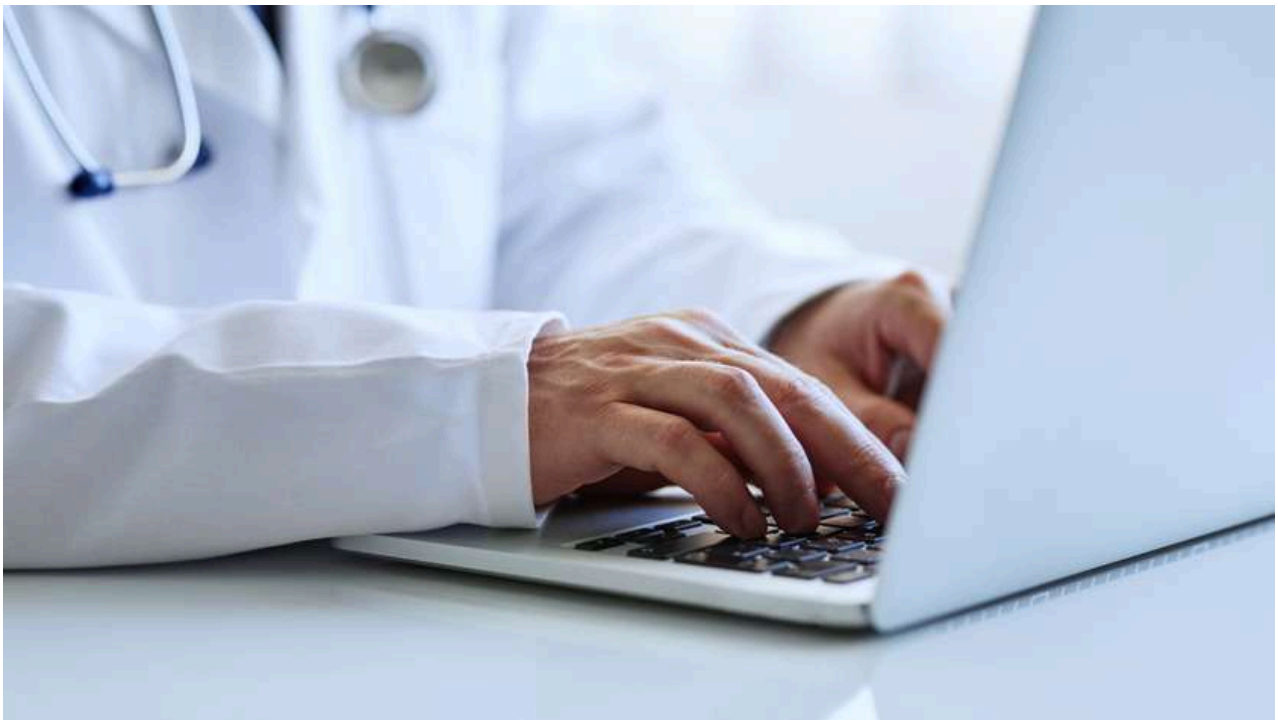
The Thalidomide scandal revealed a huge flaw in the regulatory system of the time, highlighting the lack of rigorous protocols for evaluating drug safety. The global reaction was swift. In the United States, the FDA, which had already raised concerns about the safety of Thalidomide by refusing to approve it due to the lack of adequate data, introduced even stricter regulations on clinical trials and the evaluation of teratogenic effects. In Europe, the first pharmacovigilance structures were established to monitor adverse reactions and post-marketing reports. A fundamental principle was also introduced: active pharmacovigilance, according to which a drug cannot be considered safe only at the time of approval, but must be constantly monitored over time.

THALIDOMIDE AND THE LESSON FOR DRUG SAFETY

The Thalidomide case forever changed pharmaceutical safety. Today, every drug undergoes rigorous testing before approval. But pharmacovigilance does not end there: monitoring continues even after commercialization, and the role of healthcare professionals and pharmaceutical companies is essential. Reporting an adverse drug reaction is not just a regulatory obligation, it is an act of responsibility. The Thalidomide tragedy taught us a crucial lesson: every report can make a difference.

GVP MODULE VI ADDENDUM II: HOW TO COMPLY WITH THE NEW EMA RULES ON ICSR DATA

GVP MODULE VI ADDENDUM II ISSUED BY THE EMA INTRODUCES NEW RULES ON THE PROCESSING OF PERSONAL DATA IN ICSRS (INDIVIDUAL CASE SAFETY REPORTS) SUBMITTED TO EUDRAVIGILANCE. IN THIS ARTICLE, WE EXPLAIN WHICH ICH E2B(R3) FIELDS ARE SUBJECT TO MASKING, WHICH MUST BE LEFT BLANK, AND HOW TO COMPLY.



EHAT IS GVP MODULE VI ADDENDUM II?

GVP Module VI Addendum II is a technical and operational update published by the EMA and enetered into force in July 2024 to supplement the European pharmacovigilance guidelines with new guidance on the protection of personal data in ICSRs (Individual Case Safety Reports) submitted to EudraVigilance.

The addendum was published following an audit by the EDPS (European Data Protection Supervisor), which recommended that EMA introduce a common policy on masking personal data. The goal is to strengthen privacy protection by ensuring that no information that could identify patients, reporters, or senders appears.
This update does not change the technical framework of ICSRs or the EudraVigilance business rules, but directly impacts their content. It is therefore essential for the QPPV and pharmacovigilance team to know precisely which fields should be masked, which should be left blank, and how to manage them.

ICH-E2B(R3) FIELDS TO LEAVE BLANK

The second category includes 11 ICH fields whose data is not required for signal management, duplicate detection, or ICSR processing, but contains personal data.

If filled in, these fields must be submitted to EudraVigilance blank, as the use of nullFlavors is not supported by the ICH-E2B(R3) guidelines.

The fields in question are:

- C.3.3.2 Sender's Title
- C.3.3.3 Sender's Given Name
- C.3.3.4 Sender's Middle Name
- C.3.3.5 Sender's Family Name
- C.3.4.1 Sender's Street Address
- C.3.4.2 Sender's City
- C.3.4.3 Sender's State or Province
- C.3.4.4 Sender's Postcode
- C.3.4.5 Sender's Country Code
- C.3.4.6 Sender's Telephone
- C.3.4.7 Sender's Fax

ICH-E2B(R3) FIELDS TO BE MASKED

The first category concerns 13 ICH fields. The data contained in these fields is not required for signal management, duplicate detection, or ICSR processing, but contains data that can be directly linked to an individual.

These fields, if filled in, must be masked with the nullFlavor code "MSK".
If they are not filled in, you can use the nullFlavor codes ASKU, NASK, UNK or leave the field blank.

The ICH fields in question are:

- 2.r.1.1 Reporter's Title
- 2.r.1.2 Reporter's Given Name
- 2.r.1.3 Reporter's Middle Name
- 2.r.1.4 Reporter's Family Name
- 2.r.2.1 Reporter's Organisation
- 2.r.2.2 Reporter's Department
- 2.r.2.3 Reporter's Street
- 2.r.2.6 Reporter's Postcode
- 2.r.2.7 Reporter's Telephone
- 1.1.1 Patient Medical Record Number(s) and Source(s) of the Record Number (GP
- Medical Record Number)
- 1.1.2 Patient Medical Record Number(s) and Source(s) of the Record Number
- (Specialist Record Number)
- 1.1.3 Patient Medical Record Number(s) and Source(s) of the Record Number
- (Hospital Record Number)
- 10.1 Parent Identification

ICH-E2B(R3) FIELDS THAT MAY CONTAIN PERSNALDATA BUT ARE REQUIRED FOR PHARMACOVIGILANCE PURPOSES

This category includes approximately 185 ICH and EU fields that, while they may in some cases include personal data, must not be masked or left blank as they are essential to ensure quality and the effectiveness of pharmacovigilance processes.

For the relevant fields, please refer to the official document.

ICH-E2B(R3) FIELDS THAT DO NOT CONTAIN PERSONAL DATA AND ARE REQUIRED FOR PHARMACOVIGILANCE PURPOSES

This category includes 73 ICH and EU fields that do not contain personal information and are required for signal management, duplicate detection, and ICSR processing. ICSR submitters to EudraVigilance must not mask or leave blank the data for these data elements.

For the relevant fields, please refer to the official document.

WHAT CHANGES WITH GVP MODULE VI ADDENDUM II

The addendum does not change the EV Business Rules or the ICSR XML schema. The electronic submission processes and technical guidelines remain unchanged.

The ICSR XML files already submitted will remain archived in their original form for regulatory and audit purposes. Access to this information remains limited to a small number of authorized members who can make the XML files available to Member State competent authorities for inspections of clinical trial sponsors, marketing authorization applicants, and marketing authorization holders.

EMA, however, requires that measures to comply with the Addendum be implemented as soon as possible and in any case within a reasonable timeframe.

HOW TO COMPLY WITH ADDENDUM II MODULE VI GVP: THE READY-MADE SOLUTION FOR DATA MASKING

Addendum II Module VI GVP requires ICSR submitters to mask or leave blank specific ICH-E2B(R3) fields. Without a properly configured system, this would mean having to manually edit the XML files, risking errors and delays in submitting to EudraVigilance.

SafetyDrugs, the pharmacovigilance database developed by Max Application, features a GDPR module that, in addition to its data masking functions for submitting ICSRs outside the EU, automatically ensures compliance with the Addendum. During submission to EudraVigilance, it allows:

- masking of the 13 ICH fields relating to the reporter, patient medical record number(s), and source(s) of the record number and parent identification;
- deletion of the contents of the 11 ICH fields relating to the sender.

If you would like more information on the SafetyDrugs GDPR module or to request its activation or update, please do not hesitate to contact us.

EMA HTTP SCHEMA DISABLING: HOW TO PREVENT ISSUES IN ICSR SUBMISSIONS

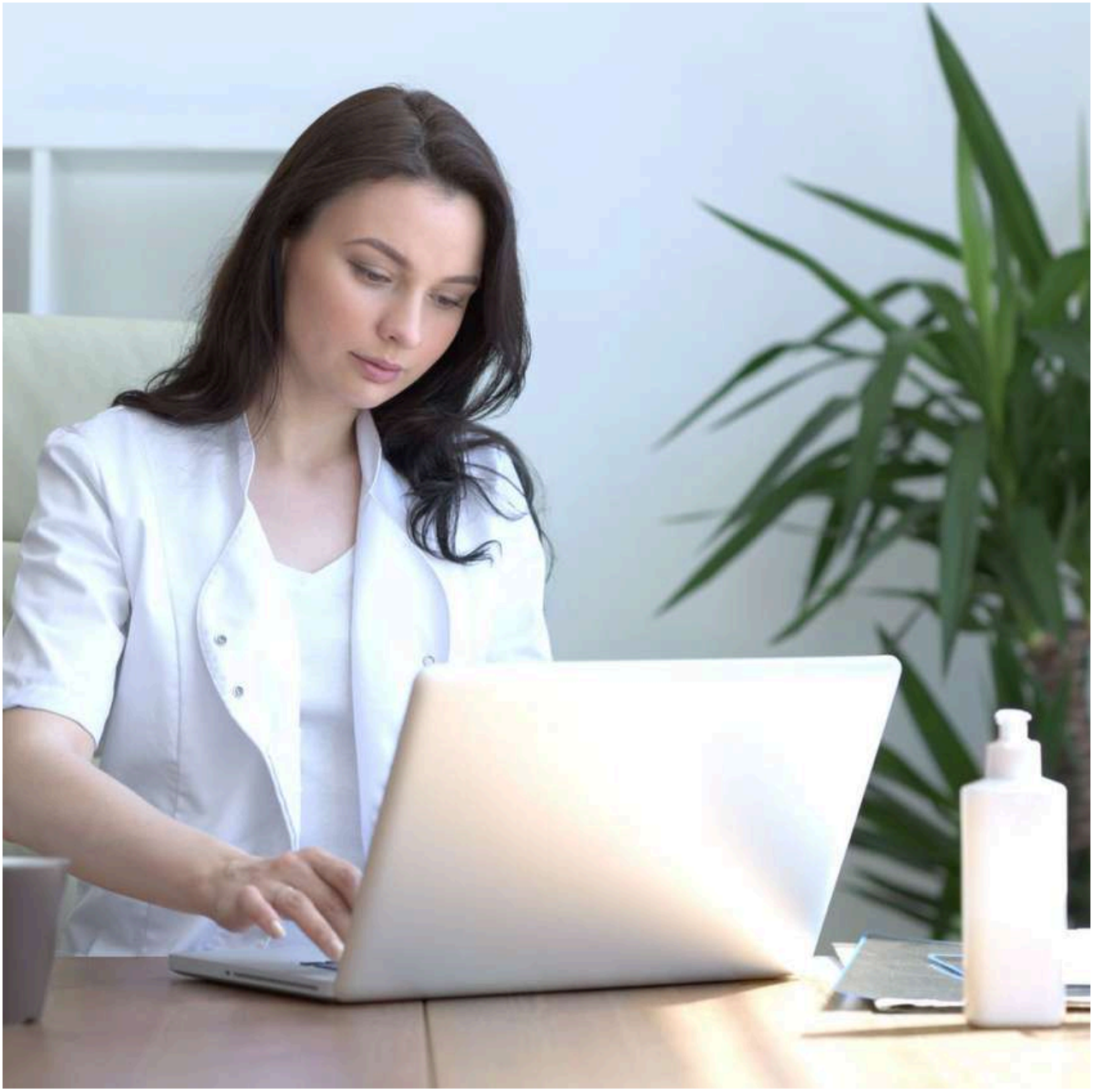
THE EUROPEAN MEDICINES AGENCY (EMA) HAS ANNOUNCED THE INITIATIVE "EUDRAVIGILANCE DISABLING HTTP SCHEMAS", INTRODUCING CHANGES TO THE TECHNICAL REFERENCES USED FOR THE SUBMISSION OF INDIVIDUAL CASE SAFETY REPORTS (ICSRS) VIA GATEWAY AND EVWEB. THIS IS A TECHNICAL UPDATE AIMED AT STRENGTHENING THE SECURITY OF DATA TRANSMISSIONS AND LIMITED TO THE MODALITIES CASES ARE SUBMITTED TO EUDRAVIGILANCE. THIS ARTICLE OUTLINES WHAT THIS CHANGE MEANS FOR PHARMACEUTICAL COMPANIES AND HOW TO ADDRESS IT IN A CONTROLLED AND STRAIGHTFORWARD MANNER.

WHY EMA IS DISABLING HTTP ACCESS TO EUDRAVIGILANCE XML SCHEMAS

EMA is progressively phasing out the use of HTTP across its online resources because this protocol requires data to be transmitted in plain text, exposing information to the risk of interception, reading or alteration during transmission. For this reason, HTTP is no longer considered suitable for the exchange of regulatory information.

As a replacement, EMA has adopted HTTPS (HTTP Secure), which enables protected data transmission and meets the security standards required for handling sensitive information.

This change also affects ICSR submissions: when cases are created in EVWEB or generated within company systems, the XML files transmitted to EudraVigilance and the related acknowledgement messages (ACKs) reference the R3 schemas, which must now be accessible exclusively via HTTPS.



WHAT CHANGES TECHNICALLY IN ICSR SUBMISSION

From a technical perspective, the content of the cases does not change. The update affects the XML header of ICSRs and ACKs, i.e. the section of the message that contains the technical references to the XML schemas (the structured format used to represent and exchange data in a standardised way). These references are used for file validation and allow EudraVigilance to correctly interpret the structure of the message.

WHO IS AFFECTED BY THE EMA HTTP SCHEMA DISABLING

Pharmaceutical companies that use their own safety database to create, manage and submit ICSRs via Gateway or via upload in EVWEB, or that download ACKs or ICSRs from EVWEB for use in their own systems, must update their XML schema references in line with EMA requirements.

ICSR SUBMISSION VIA GATEWAY

For ICSR submissions via Gateway, EMA has announced that HTTP access to the XML schemas for ICSRs and the related acknowledgements will be disabled as of:

- 15 January 2026: only HTTPS endpoints will be accepted.

ICSR SUBMISSION VIA EVWEB

When EVWEB is used as the channel for ICSR submission, EMA has defined a progressive timeline for disabling HTTP references to XML schemas. The plan includes:

- 15 January 2026: start of the testing phase. The external test environment (XCOMP) for ICSRs accepts both HTTP and HTTPS; ACKs already reference HTTPS only. The production environment continues to accept HTTP only for both ICSRs and ACKs.
- 15 April 2026: start of the optional production phase. Test and production environments accept both HTTP and HTTPS for ICSRs. ACKs reference HTTPS only.
- 15 July 2026: start of full production. Test and production environments accept HTTPS only for both ICSRs and ACKs.

POTENTIAL ISSUES IN THE ABSENCE OF ALIGNMENT WITH EMA REQUIREMENTS

Without a technical update to the systems used for ICSR submission, it will no longer be possible to complete case submissions correctly, resulting in a disruption of transmission flows.

It is therefore necessary to align with EMA requirements before the indicated deadlines in order to ensure operational continuity and regulatory alignment.

HOW TO ALIGN WITH EMA REQUIREMENTS FOR ICSR SUBMISSION

SafetyDrugs already provides the update required by EMA through a dedicated fix. The update modifies the XML header in line with EMA guidance, disabling HTTP schema references and adopting HTTPS exclusively. The SafetyDrugs solution covers both scenarios: ICSR XML generation for the uploading in EVWEB and submission via Gateway. For SafetyDrugs customers, alignment with EMA requirements is ensured through the installation of a dedicated fix.

RISK MINIMISATION MEASURES (RMMS): THE NEW APPROACH IN GVP MODULE XVI REVISION 3

RISK MINIMISATION MEASURES (RMMS) ARE AT THE CORE OF THE NEWLY RELEASED REVISION 3 OF GVP MODULE XVI. THIS UPDATED GUIDANCE REDEFINES STRATEGIES, TOOLS, AND CRITERIA TO ENABLE A MORE EFFECTIVE AND MEASURABLE APPROACH TO RISK MANAGEMENT. THESE SIGNIFICANT REGULATORY UPDATES WERE PRESENTED BY GIOVANNI DIANA (AIFA) DURING THE PHARMACOVIGILANCE SESSION AT THE 64TH AFI SYMPOSIUM.

A STRATEGIC REVISION FOR MORE EFFECTIVE RISK MANAGEMENT

Entered into force on 6 August 2024, Revision 3 of the Guideline on Good Pharmacovigilance Practices (GVP) Module XVI – Risk Minimisation Measures aims to enhance the effectiveness of RMMs by reinforcing their integration into the overall benefit–risk management lifecycle of medicinal products. The updated guidance applies to new marketing authorisations (MA), newly proposed risk minimisation measures, and new studies evaluating the effectiveness of existing RMMs. One of the core concepts highlighted is proactivity. The revision calls for a fundamental shift in the approach to RMMs, promoting preventive strategies that incorporate emerging technologies, improve risk communication, and increase patient engagement.

CRITERIA FOR INTRODUCING ADDITIONAL RISK MINIMISATION MEASURES AND SELECTING TOOLS

GVP Module XVI Revision 3 clearly states that additional risk minimisation measures (aRMMs) should only be implemented when truly necessary and proportionate. The selection of the most appropriate tool must be based on a structured assessment that considers:

- the severity and nature of the risk, to the actions required of patients and healthcare professionals (HCPs);
- the characteristics of the medicinal product, including indication, dosage, route of administration, and potential for medication errors;
- the target population (patients and HCPs), the context of use, and specific information needs;
- the impact of the RMMs on both the patient and the healthcare system, evaluating the proportionality of the burden imposed;
- the practical feasibility and expected effectiveness of the measure, avoiding unintended negative consequences.

This approach guides marketing authorisation holders (MAHs) toward an evidence-based and justified selection of tools—whether educational, digital, or operational—in alignment with the principle of regulatory appropriateness.ia.

ADAPTING EXISTING RMMS: WHEN AND WHY TO INTERVENE

GVP Module XVI Revision 3 emphasises the importance of reassessing and adapting RMMs when clinical, regulatory, or operational conditions change. Key factors that may prompt revision include:

- new pharmacovigilance data or updates to the safety profile of the medicinal product;
- modifications to the marketing authorisation (e.g., new indications, patient populations, formulations);
- results from RMM effectiveness studies, particularly regarding patient representativeness;
- the need for additional materials to maintain a positive benefit-risk balance;
- organisational or technological changes within healthcare systems;
- identification of unintended adverse consequences related to the RMMs themselves;
- international experience with the same tool or measure.

In this context, educational materials should be regarded as dynamic instruments—subject to ongoing revision and optimisation. This is the only way to ensure their continued effectiveness and relevance in real-world clinical practice.

THE CONCEPT OF "BEYOND THE LABEL"

Another key innovation is the integration of advanced tools such as big data analytics and artificial intelligence to support a proactive approach to early risk identification. This has given rise to the concept of risk minimisation beyond the label. It marks a significant paradigm shift: risk minimisation measures should not be limited to the information provided in the product documentation (e.g., Summary of Product Characteristics – SmPC, Package Leaflet – PL, labelling), but may — and in some cases must — extend beyond these boundaries.

This means that regulatory authorities or marketing authorisation holders (MAHs) can propose or implement additional, more targeted tools when standard product information alone is insufficient to ensure the safe use of the medicinal product.
Examples of *beyond the label* measures include:

- targeted training programmes for healthcare professionals (HCPs);
- clinical checklists for structured risk management;
- educational campaigns for patients with complex conditions;
- digital alerts or clinical decision support tools.

The *beyond the label* approach recognises that, to be effective, RMMs must be tailored to real-world clinical and organisational settings — moving beyond regulatory documentation into tangible practice.

DIGITAL TECHNOLOGIES: NEW OPPORTUNITIES FOR RISK COMMUNICATION

Revision 3 of the GVP Module XVI highlights the growing role of digital technologies in managing educational materials and communicating risk. Mobile apps, QR codes, online platforms, and Real-World Evidence (RWE) are increasingly seen as key tools to enhance adverse event reporting, enable continuous monitoring, and improve the dissemination of regulatory content.

In this context, the CMDh position paper supports the use of mobile technologies in official product information (SmPC, labelling, PL). Marketing authorisation holders (MAHs) may choose, on a country-by-country basis, to integrate mobile scanning features that provide direct access to digital educational materials — a step that may become mandatory in the future.

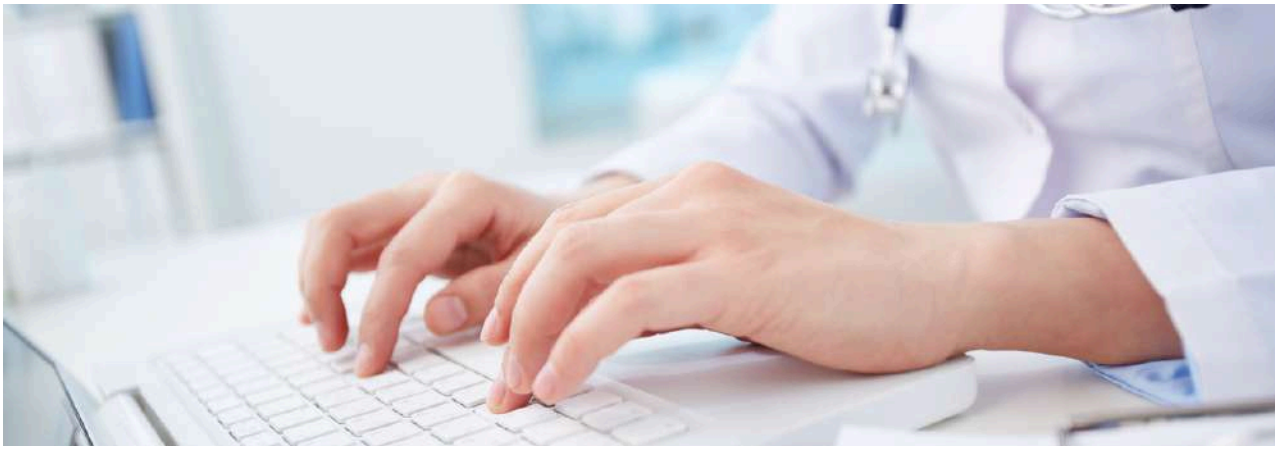
ACCESSIBILITY, DIGITAL DIVIDE, AND REGULATORY CHOICES: A MULTICHANNEL STRATEGY

While digital solutions open up new opportunities to make educational materials more accessible and tailored, they also raise critical challenges that cannot be overlooked. GVP Rev. 3 emphasises the importance of addressing the digital divide — disparities in access to and use of technology, which may stem not only from technical limitations but also from cultural, cognitive, or linguistic barriers.

To ensure truly effective risk communication, companies must adopt a multichannel approach, deploying digital tools only when they are appropriate for the intended population. Where necessary, traditional channels should be maintained or strengthened.

The selection of digital tools for educational materials should be based on a structured assessment, taking into account the medicinal product's therapeutic profile, the composition of the at-risk population, the nature of the risk to be communicated, technical feasibility, and the acceptability among stakeholders.

Finally, the revision underscores the need for international regulatory cooperation to harmonise RMM strategies and ensure that safety information is understandable and accessible across global markets.



PATIENT-CENTRIC PHARMACOVIGILANCE: ENGAGING PATIENTS AND HCPS

The revised GVP Module XVI promotes a patient-centric approach to pharmacovigilance, where individuals are not merely passive recipients of information but active participants in the risk management process.

Key innovations include:

- direct adverse event reporting by patients;
- evaluation of RMM effectiveness through surveys and focus groups;
- co-creation of educational materials with both HCPs and patients.

CONTINUOUS TRAINING AND NEW TOOLS: STRENGTHENING COMPLIANCE THROUGH EDUCATION

The updated GVP Module XVI introduces mandatory continuous training programs for all personnel involved in pharmacovigilance activities. These programs are expected to adopt hybrid and multichannel formats, including in-person sessions, online platforms, and video tutorials. This emphasis on ongoing education reinforces the connection between regulatory compliance and the consistent application of good clinical practice in everyday healthcare settings.

NEW DEFINITIONS: CLEARER AND MORE STRUCTURED RMM MESSAGES AND TOOLS

Among the updates introduced in Revision 3 is the inclusion of new official definitions aimed at enhancing clarity and consistency in the design and implementation of risk minimisation measures (RMMs).
Specifically:

- RMM Messages refer to key risk-related informational content, i.e. specific instructions for patients and healthcare professionals (HCPs) on actions to take to reduce the risk associated with a given medicinal product.
- RMM Tools are the instruments used to deliver those safety messages. They fall into two main categories:
    - Educational tools, such as risk minimisation guides, checklists, patient cards, or diaries for continuous patient monitoring;
    - Monitoring and control tools, which are more structured and formal, designed to ensure actual control over the medicinal product's use, especially in complex settings. Examples include: supply chain traceability systems, documented exchange of patient-related information (e.g. test results between HCPs), or qualification requirements for HCPs involved in prescribing, administering, or dispensing the drug.

This new classification framework aims to improve traceability and measurability of RMM effectiveness, while supporting a modular and adaptable approach across varying clinical, technological, and regulatory contexts.

A NEW OPERATIONAL FLOW FOR RMM MANAGEMENT: FROM DESIGN TO EVALUATION

One of the most significant innovations introduced by Revision 3 of GVP Module XVI is the structured, cyclical approach to managing risk minimisation measures (RMMs). The updated process is articulated in five sequential phases:

1. Regulatory implementation of RMMs: During the marketing authorisation (MA) process, appropriate RMMs are defined and approved for each medicinal product.
2. Dissemination to the target population: Educational materials and control tools are distributed to patients, healthcare professionals (HCPs), and other stakeholders involved in the medicinal product's use.
3. Knowledge acquisition and attitude change: Recipients must comprehend the key messages, internalise their content, and adjust their risk perception accordingly.
4. Adoption of expected behaviours: Understanding must translate into concrete actions, such as following specific instructions, avoiding high-risk practices, or adhering to monitoring protocols.
5. Improvement of health outcomes: The proper application of RMMs should lead to reduced medicinal risk, prevention of adverse events, and safer therapeutic use.

This framework underscores the need for continuous monitoring and feedback to ensure the effectiveness of each phase and the overall success of the RMM strategy.

NEW PERSPECTIVES: VISUAL IDENTITY AND STANDARDISATION OF RMM MATERIALS

Looking ahead, Revision 3 also outlines concrete developments in the design and dissemination of risk minimisation measures. Two main directions are emerging:

- Standardisation of RMM material naming conventions: To facilitate the identification and management of educational materials across various regulatory and healthcare contexts, the adoption of a harmonised, clear, and systematic nomenclature is encouraged. This would enhance communication between marketing authorisation holders (MAHs), competent authorities, and healthcare professionals.
- Introduction of an official visual identifier for educational materials, modelled on Germany's Blaue Hand initiative (by BfArM). This recognisable, authoritative symbol — validated by the relevant authority — would allow both patients and HCPs to immediately identify RMM-approved materials.

These forward-looking proposals highlight the need to make pharmacovigilance not only effective but also visible, understandable, and recognisable to all stakeholders involved.

EVALUATING RMM EFFECTIVENESS: FROM CLINICAL CONTEXT TO EXPECTED OUTCOMES

Another key focus of GVP Module XVI Revision 3 is the evaluation of the effectiveness of RMMs. Implementing tools and materials alone is not sufficient — it is essential to assess whether they reach the intended target population, are understood, and result in meaningful changes in health-related behaviour.

To support this assessment, the guidance highlights the need to understand the medicinal product's use context, including clinical workflows, organisational settings, and patient characteristics. Mapping this context helps identify factors that may support or limit RMM success, such as information flow, health literacy, and patterns of care.

The expected outcomes of an effective RMM are:

1. Reach: the measure reaches the intended target population
2. Behavioural impact: patients and/or healthcare professionals adopt risk-minimising behaviours;
3. Clinical benefit: measurable improvement in health outcomes, such as reduced incidence or severity of adverse reactions.

EFFECTIVENESS ASSESSMENT METHODS: QUANTITATIVE, QUALITATIVE AND MULTI-LEVEL APPROACHES

To measure these outcomes, two complementary approaches are proposed:

- Quantitative methods, which assess the distribution and uptake of risk communication materials, helping to identify potential barriers or distribution gaps.
- Qualitative methods, which explore how the target population perceives the risk, understands the safety messages, and what drives adherence or resistance to the proposed measures.

These assessments can be conducted through structured interviews, focus groups, or surveys, and are considered a critical phase to ensure RMMs translate into real-world impact in both clinical practice and patient lives.

The GVP guidelines stress the importance of conducting effectiveness evaluations at every stage of the RMM lifecycle, with attention to both:

- Intended outcomes, such as behaviour change or reduction of adverse drug reactions (ADRs),
- unintended consequences, such as misinterpretations or cultural barriers.

A structured, multi-step evaluation process is recommended:

1. Coverage and distribution of the materials (e.g., receipt rates, web analytics, channel monitoring).
2. Knowledge and attitudes of the target population (e.g., surveys on risk awareness, interviews on message retention).
3. Behavioural changes (e.g., correct adherence to therapy, proper use of provided tools).
4. Clinical outcomes and unforeseen effects, which must also be tracked and integrated into the final analysis.

This multi-dimensional perspective reinforces a proactive and iterative model of pharmacovigilance, where the success of RMMs is not judged solely by clinical outcomes, but also by the ability to detect indirect signals and continuously enhance risk communication strategies.

IMPLICATIONS FOR PHARMACEUTICAL COMPANIES: STRATEGY, EVIDENCE AND INCLUSIVENESS

Revision 3 of GVP Module XVI represents a paradigm shift in the management of risk minimisation measures (RMMs), elevating them from a mere regulatory requirement to strategic, dynamic tools with measurable impact. For pharmaceutical companies, this means rethinking existing processes: it is no longer sufficient to simply distribute educational materials — companies must now provide documented evidence that RMMs effectively reach target populations, influence behaviour, and improve health outcomes.

This calls for structured, multidisciplinary planning across the entire lifecycle of RMMs — from design to implementation and evaluation. Key elements include the customisation of content, selection of the most effective communication channels, and the long-term sustainability of the chosen strategies. Companies are expected to engage more closely with regulatory authorities and, equally importantly, to listen to both patients and healthcare professionals, co-developing relevant and accessible solutions.

Ultimately, the new GVP XVI encourages companies to turn compliance into value — an opportunity to build trust, enhance the safety profile of their products, and contribute to a more modern, inclusive, and genuinely effective pharmacovigilance system.

RISK COMMUNICATION IN PHARMACOVIGILANCE: A NEW APPROACH TO MANAGING EMS AND DHPCS

HOW CAN RISK COMMUNICATION IN PHARMACOVIGILANCE EVOLVE TOWARD MORE EFFECTIVE, TRACEABLE, AND SUSTAINABLE MODELS? ALTHOUGH THE EU GOOD PHARMACOVIGILANCE PRACTICES (GVP) OFFER A HARMONIZED REGULATORY FRAMEWORK, IMPLEMENTATION VARIES SIGNIFICANTLY ACROSS MEMBER STATES. ITALY, IN PARTICULAR, PRESENTS A FRAGMENTED LANDSCAPE THAT ILLUSTRATES THE URGENT NEED FOR INNOVATION. IN THIS ARTICLE, WE EXAMINE THE KEY FINDINGS AND PROPOSALS FROM THE "RETHINK SAFETY COMMUNICATION" PROJECT—AN INITIATIVE DEVELOPED BY A MULTIDISCIPLINARY WORKING GROUP AND PRESENTED DURING ITALY'S NATIONAL AFI SYMPOSIUM 2025.

A COLLABORATIVE INITIATIVE TO IMPROVE RISK COMMUNICATION IN PHARMACOVIGILANCE

"Rethink Safety Communication" is a project presented during the pharmacovigilance session of the AFI Symposium 2025. It was promoted by a working group composed of Cittadinanzattiva, F.A.V.O. (Italian Federation of Volunteer Oncology Associations), the Federation of Italian Pharmacists' Orders (FOFI), Federfarma, FISM (Federation of Italian Medical-Scientific Societies), SIFO (Italian Society of Hospital Pharmacy and Pharmaceutical Services of Healthcare Organizations), UNIAMO (Italian Federation for Rare Diseases), AFI (Italian Association of Pharmaceutical Industry Professionals), and IQVIA.

The goal: to analyze the current national approach to managing Educational Risk Minimisation Materials (EMs) and Direct Healthcare Professional Communications (DHPCs), benchmark it against best practices in other EU countries, and outline a scalable, digitally driven model that could serve as a reference for wider adoption.

The methodology included:

1. Regulatory analysis of the EU GVPs;
2. A survey involving 27 Roche affiliates across Europe;
3. In-depth reviews of five key national frameworks (Finland, France, Germany, Spain, UK) and Italy;
4. Interviews with working group affiliates in those countries;
5. Discussions with Italian healthcare stakeholders;
6. A multidisciplinary think tank for collecting insights.

The resulting position paper "Rethink Safety Communication: A new way to disseminate aRMM and DHPC" outlines a phased strategy to modernize risk communication in Italy and potentially beyond.

KEY CHALLENGES IN THE CURRENT ITALIAN MODEL

Although GVPs define a harmonized foundation, their implementation is left to national discretion, leading to varied levels of maturity across EU Member States. While several countries have adopted centralized digital infrastructures, Italy still relies on fragmented and paper-based systems.

Within this context, the dissemination of Educational Materials and Direct Healthcare Professional Communications presents critical inefficiencies. Communications concerning the same active substance are often issued independently by multiple MAHs, using inconsistent formats and delivery methods —resulting in information overload and lack of clarity.

EMs are frequently difficult to distinguish from promotional content, lacking standardized layouts and visual cues to highlight key safety messages. Visual recognition—an essential factor for capturing attention in clinical workflows—remains underutilized.

Printed materials continue to dominate, particularly for patient-oriented communications. This generates a number of operational drawbacks: high production costs, long lead times, and complex logistics.

More importantly, traceability is extremely limited. There is no reliable way to confirm whether a document was received, when it was delivered, or whether it was understood.

Every update requires a new print run, increasing the risk that outdated versions remain in circulation.

In 2024 alone, the companies involved in the "Rethink Safety Communication" project distributed more than 8.7 million sheets—equivalent to 43.6 tons of paper—raising clear concerns about environmental sustainability and process efficiency.

Italy also lacks a centralized institutional repository. While other EU countries provide searchable digital platforms, Italian DHPCs are posted as press releases on the AIFA website, and EMs are partially tracked in a static Excel file—limited to patient cards. This setup lacks real-time access, completeness, and transparency.
Furthermore, integration with healthcare IT systems is minimal. Approved EMs and NIIs are not linked to the software used in prescribing or dispensing, hindering point-of-care access to the most up-to-date safety information.
These structural weaknesses limit the effectiveness, measurability, and patient-centricity of risk communication—even when formal GVP compliance is in place.

PROPOSALS FROM THE WORKING GROUP: TOWARDS DIGITAL AND STAKEHOLDER-ORIENTED SOLUTIONS

Based on the analysis conducted, the AFI working group developed a set of actionable proposals to overcome the challenges identified.

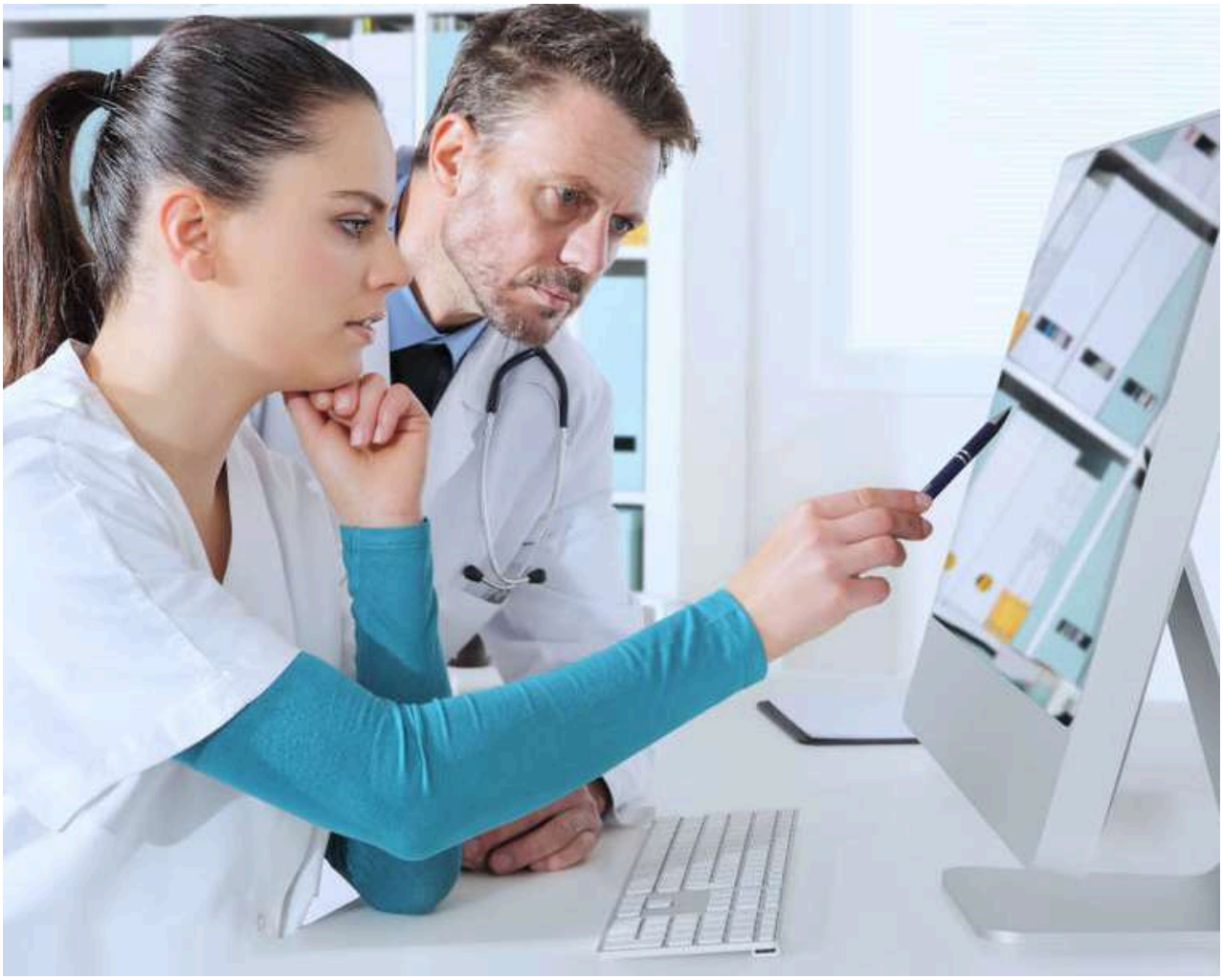
A top priority is the establishment of a centralized institutional repository, managed by AIFA, the Italian authority, or an authorized entity. This repository would consolidate all approved EMs and DHPCs in a single platform, with tailored access levels for healthcare professionals and patients, advanced search functions, printable formats, usage analytics and interoperability with clinical and hospital IT systems.

A second recommendation is to standardize the structure and design of safety communications. All materials should use consistent formatting, a clear tone of voice, and a visual identity that immediately distinguishes them from promotional content, for example, with color codes or pictograms (e.g. a blue hand for EMs and a red hand for DHPCs). Summaries of key messages and QR codes linking to the most updated version would further enhance traceability and usability.

The project also emphasizes the importance of valuing the role of healthcare professionals and local field staff in the dissemination of safety communications. Verbal explanation during the delivery of printed or digital materials is considered essential to support comprehension. Training programs should also be strengthened to help all stakeholders — including patient associations — understand the purpose and relevance of EMs and DHPCs.

Finally, a particularly strategic aspect concerns the integration of EMs and DHPCs into healthcare IT systems. This includes features such as contextual alerts at the moment of prescribing, automatic updates via repository synchronization, tracking of consultation rates and early communication in special regulatory programs (e.g. compassionate use or early access pathways).

MEDDRA: WHAT IT IS AND WHY IT IS ESSENTIAL IN PHARMACOVIGILANCE



THE CODING OF ADVERSE EVENTS IS A CRUCIAL STEP IN PHARMACOVIGILANCE: SELECTING THE CORRECT TERM ENSURES THAT DATA ARE CLEAR, COMPARABLE, AND USEFUL FOR IDENTIFYING SAFETY SIGNALS. MEDDRA IS THE INTERNATIONAL STANDARD THAT ENABLES THIS PROCESS. IN THIS ARTICLE, WE EXPLORE ITS STRUCTURE, HIERARCHICAL LOGIC, AND OPERATIONAL IMPORTANCE FOR PROFESSIONALS IN THE FIELD.

WHAT IS MEDDRA?

MedDRA (Medical Dictionary for Regulatory Activities) is the standardized medical-regulatory terminology used internationally to code, classify, and analyze information related to adverse events, adverse reactions, medical conditions, clinical test results, and device malfunctions.

MedDRA terminology was introduced in the 1990s by the ICH (International Council for Harmonisation) to harmonize international communication in the medical regulatory field. Before that, the sector relied on multiple terminological systems such as WHO-ART© (World Health Organization's Adverse Reaction Terminology), ICD-9 (International Classification of Diseases Ninth Revision), and COSTART© (FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms). This fragmentation made data retrieval, cross-referencing, and analysis difficult.

The adoption of MedDRA overcame these limitations by offering a common, precise, and constantly updated language. The first version, MedDRA Version 1.0, was developed using the terminology of the British MCA authority (now MHRA – Medicines and Healthcare products Regulatory Agency). The second version, MedDRA Version 2.0, was the first officially adopted and implemented version.

WHERE IS MEDDRA APPLIED?

MedDRA terminology is used throughout the entire lifecycle of medicinal products for human use. In clinical settings, it is applied for coding adverse events and clinical test results in phase I, II, III, and IV studies, ensuring consistency and accuracy in data collection.

In post-marketing pharmacovigilance, MedDRA is the standard for coding spontaneously reported adverse reactions, managing Individual Case Safety Reports (ICSRs), and compiling periodic safety update reports (PSURs/PBRERs). The terminology is also mandatory in regulatory documentation submitted to health authorities (EMA, FDA, PMDA, and others) for marketing authorization applications, variations, and renewals.

MedDRA is used for monitoring and managing adverse events related to medical devices, codifying both malfunctions and their clinical consequences for patients. Additionally, in certain regulatory contexts — such as the monitoring of cosmetics or food supplements subject to surveillance — MedDRA can be employed as a common language for standardizing the description of relevant clinical events and conditions.
MedDRA covers a broad range of medical and regulatory concepts, including symptoms, diseases, diagnoses, therapeutic indications, device malfunctions (e.g., PT Device-related infection, PT Device failure), and even social circumstances relevant to regulatory assessments (e.g., PT Travel abroad or HLT Tobacco use). This breadth makes MedDRA an essential tool for complete and structured data coding.

MEDDRA HIERARCHY STRUCTURE

One of MedDRA's strengths is its hierarchical structure, designed to ensure that safety reports and analyses are consistent and easy to navigate. Each term can be explored across different levels of specificity, from broad categories to more detailed terms. The hierarchy consists of five levels: SOC (System Organ Class), HLGT (High-Level Group Term), HLT (High-Level Term), PT (Preferred Term), and LLT (Lowest Level Term).

SOC and SOC Groups (System Organ Class)

ISOC represents the highest level of the MedDRA hierarchy and groups terms based on etiology, purpose, and site of manifestation. An example is the SOC "Nervous system disorders," which includes all terms related to neurological conditions.

Related SOCs are further grouped into thematic categories to enable broader and more complete analyses across related functional areas. In total, there are 27 SOCs, each with a specific role in the classification and analysis of safety data. For example, the SOCs "Renal and urinary disorders" and "Metabolism and nutrition disorders" belong to the same functional group related to metabolic and renal functions.

It is important to note that a single SOC group can be linked to an unlimited number of HLGTs, allowing for a multi-axial view of adverse events.

HLGT (High Level Group Term)

HLGTs represent the second hierarchical level of MedDRA and organize groups of clinically related events within each SOC. These groupings facilitate data retrieval and enable targeted analysis by therapeutic area or biological function. For example, within the SOC "Nervous system disorders," the HLGT "Neurological disorders NEC" (not elsewhere classified) groups neurological conditions that are not included in other specific categories. HLGTs play a key role in supporting data presentation and extraction.

Each HLGT must be linked to at least one SOC and one HLT. There are no limits to the number of SOCs an HLGT can be associated with, providing flexibility that reflects the complexity of clinical manifestations.

HLT (High Level Term)

HLTs constitute the third level of the MedDRA hierarchy and represent specific subgroups within each HLGT. Each HLT serves as an inclusive category that gathers PTs (Preferred Terms) connected by clinical, anatomical, physiological, etiological, or functional affinities.

For example, within the HLGT "Neurological disorders NEC," we find the HLT "Paresthesias and dysesthesias," which groups terms related to sensory disturbances such as tingling, altered sensations, and abnormal feelings. This level of detail allows for more precise analysis and structured data organization.

Each HLT must be linked to at least one SOC group through an HLGT. Furthermore, an HLT can only be associated with one HLGT per SOC, ensuring a clear and linear hierarchical path. All HLTs connected to a given HLGT will automatically appear in each SOC to which that HLGT is linked, allowing for a comprehensive view of data.

PT (Preferred Term)

PTs represent the fundamental level for coding adverse events within MedDRA and are the primary coding terms used in pharmacovigilance. They distinctly describe a specific event, such as a symptom, clinical sign, disease, diagnosis, therapeutic indication, investigation, medical or surgical procedure, or relevant family, social, or medical history characteristic.

The PT follows the principle of equivalence, grouping synonyms or closely related terms under a single label, ensuring consistency and clarity in coding and interpretation. An example of a PT is "Burning sensation."

Each PT must be linked to at least one LLT (Lowest Level Term) and can have an unlimited number of LLTs associated with it, representing terminological variants, synonyms, or abbreviations.

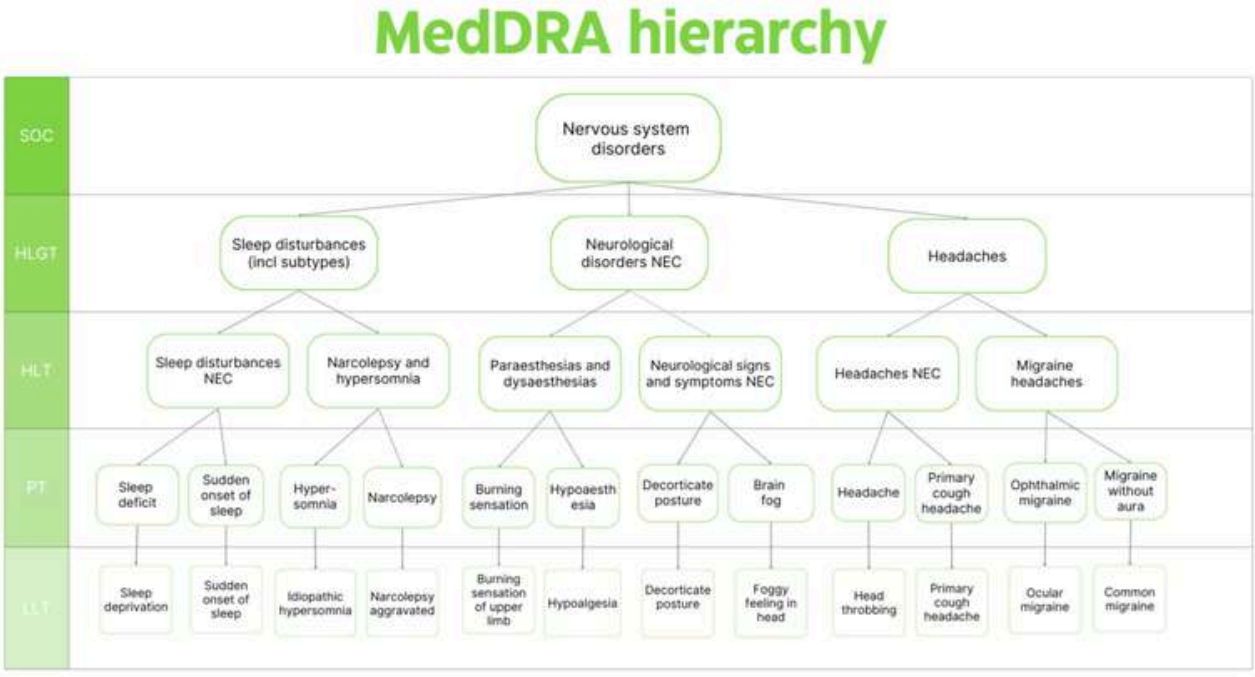
To avoid duplication during data retrieval, each PT is assigned to a primary SOC, although it may appear in multiple SOCs thanks to multi-axiality. This system allows for both coherence and flexibility, accommodating different clinical and regulatory perspectives.

LLT (Lowest Level Term)

LLTs are the most granular and detailed level of the MedDRA hierarchy. They include synonyms, near-synonyms, lexical variants, colloquial or more descriptive forms of the associated PT, and LLTs identical to the PT itself. An example of an LLT is “Burning sensation in limbs,” which allows for the coding of a more specific clinical description reported in a safety case.

This granularity allows reports to be coded exactly as they are described in clinical practice while maintaining consistency and standardization. Each LLT is uniquely linked to a single PT and cannot be associated with multiple terms, ensuring precision and clarity in the coding process.

Below we show an example of a MedDRA hierarchy tree to illustrate the levels. This is a simplified and non-exhaustive example of the MedDRA structure, as each level (SOC, HLGT, HLT, PT, LLT) actually includes hundreds or thousands of terms connected through clinical, anatomical, physiological, and etiological criteria. Furthermore, thanks to multi-axiality, each term can be associated with multiple SOCs, reflecting the complexity of clinical manifestations and the need for cross-sectional and in-depth analyses of pharmacovigilance data.

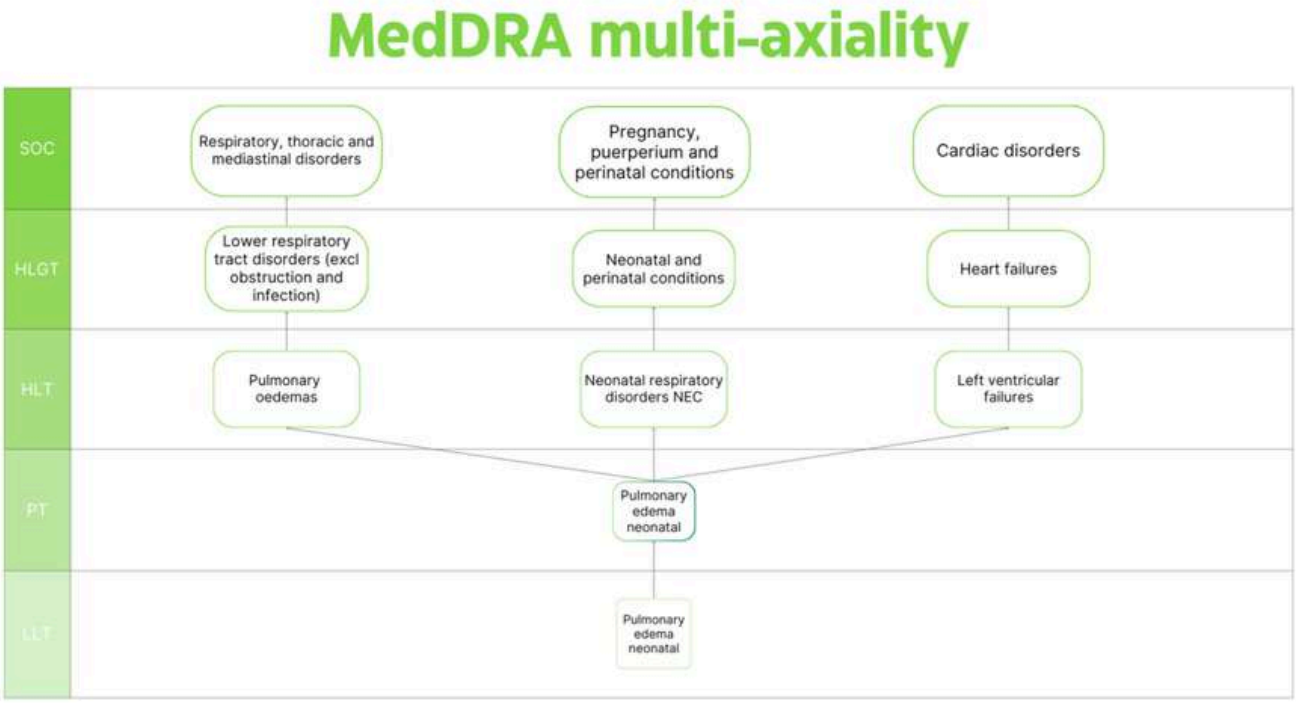


The MedDRA hierarchy represented is a simplified example: each level contains many more terms and, thanks to multi-axiality, a term can be linked to multiple SOCs to reflect the clinical complexity of events. Terms shown are based on MedDRA version 27.1.

MEDDRA MULTI-AXIALITY AND WHY IS IT IMPORTANT?

As mentioned above, the MedDRA dictionary is characterized by multi-axiality. This feature refers to the possibility that a single term belongs to multiple SOCs, reflecting clinical complexity. Many events cannot be confined to a single SOC, because their clinical manifestations may involve multiple organ systems.

PTo illustrate the concept of multi-axiality, here is a practical example: the term "Neonatal pulmonary edema" belongs to multiple SOCs: "Respiratory, thoracic and mediastinal disorders," "Pregnancy, puerperium and perinatal conditions," and "Cardiac disorders." This characteristic allows the same event to be analyzed from different perspectives, improving the ability to detect and interpret safety signals.



Example of multi-axiality: the term "Neonatal pulmonary edema" belongs to three different SOCs, demonstrating the complexity and flexibility of the MedDRA structure. Terms shown are based on MedDRA version 27.1.

MEDDRA CODES

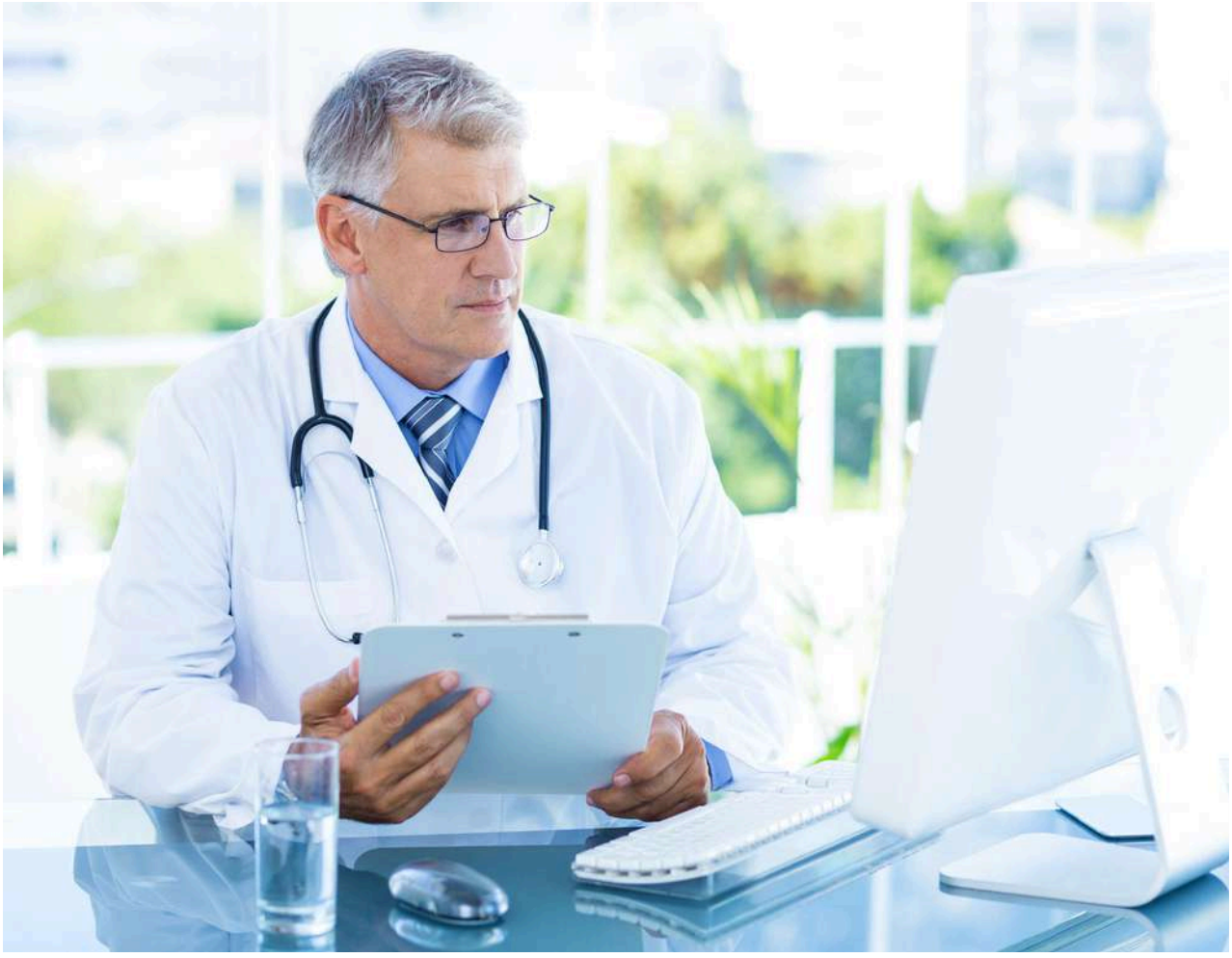
Each MedDRA term is identified by a unique eight-digit numerical code. These codes have no intrinsic meaning; they do not convey information about the term itself but serve solely as stable identifiers to ensure accuracy, traceability, and consistency over time.

Initially, codes were assigned in alphabetical order, starting with the number 10000001. As new terms are added to the system, codes are assigned sequentially. Generally, codes are not reused, except in specific cases where minor corrections are made, such as spelling corrections or formal updates to term names. In such cases, the code may be retained to ensure continuity and consistency in pharmacovigilance databases.

SMQ (Standardised MedDRA Queries)

SMQs (Standardised MedDRA Queries) are structured sets of MedDRA terms, generally selected at the Preferred Term (PT) level, that represent specific medical conditions or areas of clinical interest. These groupings are designed to facilitate the search, identification, and retrieval of potentially relevant cases from pharmacovigilance databases.

SMQs enable more efficient and focused analyses, supporting signal detection and regulatory review activities. They are essential tools for standardizing the approach to identifying critical events, allowing for more precise monitoring and more timely risk management.



MEDDRA UPDATES: A CONTINUOS IMPROVEMENT CYCLE

The Maintenance and Support Services Organization (MSSO) releases a new version of MedDRA twice a year, in March and September. The English versions are published first, followed by localized versions, including Italian, a few weeks later. These updates allow for:

- The inclusion of new medical conditions or emerging safety issues;
- Refinement or correction of existing terms;
- Revisions of multi-axial relationships to reflect new clinical evidence.

Updates can also occur in extraordinary cases. For instance, during the COVID-19 pandemic, the committee promptly added new terms in version 23.0.

MEDDRA: THE RESPONSIBILTY OF COMPANIES ENGAGED IN PHARMACOVIGILANCE

For companies involved in pharmacovigilance, keeping their systems aligned with the latest MedDRA version is an essential requirement. This involves:

1. Downloading the updated files from the MedDRA portal (a valid license is required);
2. Uploading the files into their pharmacovigilance systems;
3. Verifying the alignment of existing historical data.

Using an outdated version can lead to regulatory reporting errors, data inconsistencies, and hinder safety analyses. Every coding error can result in a missed signal or unjustified safety alarm.

WHY IS MEDDRA ESSENTIAL IN PHARMACOVIGILANCE

The use of MedDRA is a true quality and strategic tool in pharmacovigilance data management. A correct and up-to-date use of MedDRA allows you to:

- Make safety reports clearer and more analyzable, reducing interpretation errors;
- Facilitate the detection of safety signals thanks to its hierarchical and multi-axial structure;
- Ensure data comparability across different markets, overcoming linguistic barriers;
- Integrate seamlessly with pharmacovigilance systems (such as EudraVigilance and FAERS).

MEDDRA AND REPORTING QUALITY: OUR SUPPORT

Managing each update can be complex. For this reason, we offer a free service of uploading the new MedDRA release into the safety database on the official scheduled release date. This allows pharmacovigilance teams to focus on clinical case interpretation, confident that they are always working with an updated and compliant data set.

The conscious use of MedDRA, regularly updated and integrated into company processes, is not just a regulatory obligation but a critical factor for the quality, timeliness, and reliability of pharmacovigilance activities.

MEDDRA 28.0: WHAT'S NEW IN THE LATEST VERSION

MEDDRA 28.0 HAS BEEN RELEASED: THE LATEST VERSION OF THE INTERNATIONALLY ADOPTED MEDICAL REGULATORY DICTIONARY USED FOR CODING ADVERSE EVENTS AND ANALYZING SAFETY DATA. THIS BIANNUAL UPDATE INTRODUCES NEW TERMINOLOGY, HIERARCHICAL REVISIONS, AND FUNCTIONAL IMPROVEMENTS THAT REFLECT THE EVOLUTION OF CLINICAL PRACTICE AND REGULATORY REQUIREMENTS.

WHAT'S New IN MEDDRA 28.0?

Every six months, the Maintenance and Support Services Organization (MSSO) releases an updated version of MedDRA. Changes are based on user-submitted update requests, proactive proposals, and internal reviews.

For version 28.0, 1,620 change requests were reviewed, of which 1,207 were approved and implemented, while 411 were rejected and two requests were temporarily suspended for further evaluation in subsequent releases.

The main new features of MedDRA 28.0 include:

- terminology updates at all levels of the hierarchy;
- complex changes;
- SMQ updates;
- proactive interventions on terminology placements;
- expansion of available languages;
- updates to the Web-Based Browser (WBB) and the MVAT tool.
- updates to the Points to Consider (PtC) Document
- advancements on mapping initiatives

MEDDRA 28.0 TERMINOLOGY UPDATES

The approved changes affect all MedDRA hierarchy levels: SOC, HLGT, HLT, PT, and LLT. Key interventions include:

- 789 new LLTs
- 291 new PTs
- 23 promotions from LLT to PT
- 35 demotions
- 151 LLTs reassigned under different PTs
- 17 LLTs and 5 PTs assigned a new Primary SOC
- 1 MedDRA term variation
- 2 currency changes
- 3 complex changes

To help users identify changes between versions, MedDRA offers the Version Analysis Tool (MVAT), a web-based tool to compare any two versions, including non-sequential ones.

COMPLEX CHANGES

Among the most notable updates are two new HLTs:

- “Quality system issues”, under the SOC “Product issues”;
- “Rhabdoviral infections”, under “Infections and infestations”, which incorporates the previously separate HLT “Rabies viral infections”.

SMQ UPDATES AND SUSPENSIONS

No new Standardised MedDRA Queries (SMQs) were added in version 28.0. However:

- 289 PT modifications;
- 678 LLT modifications were made within existing SMQs.

The development of a new SMQ related to neurodevelopmental disorders has been temporarily suspended due to methodological considerations.

PROACTIVITY REQUESTS: ENHANCING CLASSIFICATION COSISTENCY

Proactivity requests allow users to highlight critical issues and suggest corrections or improvements. MSSO has implemented two proposals in this release:

- HLT Sexual Issues: The LLT "Not Sexually Active" has been moved to the PT "Sexual Abstinence" (sexuality issues – not sexually active – sexual abstinence);
- HLGT Sleep Disorders and Disturbances: 23 changes have been implemented, including the addition of the new PT "Sleep Disorders and Disturbances – sleep-related breathing disorders."

MEDDRA IN NEW LANGUAGES

With the release of version 28.0, Icelandic has been added, bringing the total number of supported languages to 24.

Translations into Bulgarian, Maltese, Norwegian, Romanian, Slovak, and Slovenian are underway, expanding accessibility and supporting the use of MedDRA in multilingual regulatory environments.

WEB-BASED BROWSER MEDDRA

An important technical update accompanies this release: the MedDRA Web-Based Browser (WBB) has been completely redesigned.

New features and improvements include:

- A cleaner, more intuitive user interface
- Integrated MVAT tool
- Ability to submit translation change requests
- Display of mapping status for selected terms
- Direct submission of change proposals from the browser
- Optimized term search
- Interface and language customization

A significant step forward for those who consult the MedDRA dictionary frequently and strategically.

POINTS TO CONSIDER (PTC) DOCUMENT UPDATES

With MedDRA 28.0, the PtC documents, published by ICH, have also been updated. These practical guidelines address not only term selection but also data retrieval and presentation strategies.

The PtC for term selection has undergone minor editorial changes to align with its companion document. Specifically, some sections related to patient outcomes were updated to ensure consistent use of "serious criteria" terminology. These changes are minimal and do not affect the practical use of the document.

More significantly, the companion PtC document has been released in version 3.0, responding to user feedback requesting more in-depth guidance on specific topics. This version updates sections 1–4 (Introduction, Data Quality, Medication Errors, Product Quality Issues) and introduces a new section 5: Manufacturing and Quality System Issues This new section provides practical guidance on coding deviations and nonconformities in manufacturing processes, including examples for real-world scenarios.

The update significantly enhances support for users operating in complex regulatory and production environments.

MEDDRA AND INTEROPERABILITY: UPDATES ON MAPPING INITIATIVES

In addition to document updates, activities are also underway regarding MedDRA mapping, i.e., activities aimed at building relationships between MedDRA and other healthcare terminologies. This strategic effort is designed to foster interoperability between regulatory systems and streamline communication between bodies adopting different standards.

One of the activities currently underway concerns the mapping between ICD-11 and MedDRA, carried out in collaboration with the World Health Organization (WHO). The project involves the progressive mapping of the systemic chapters of the ICD-11 classification and is being jointly managed by WHO and MSSO on behalf of ICH. The goal is to facilitate conceptual alignment between the two terminological frameworks, particularly for the retrieval and coding of clinical events.

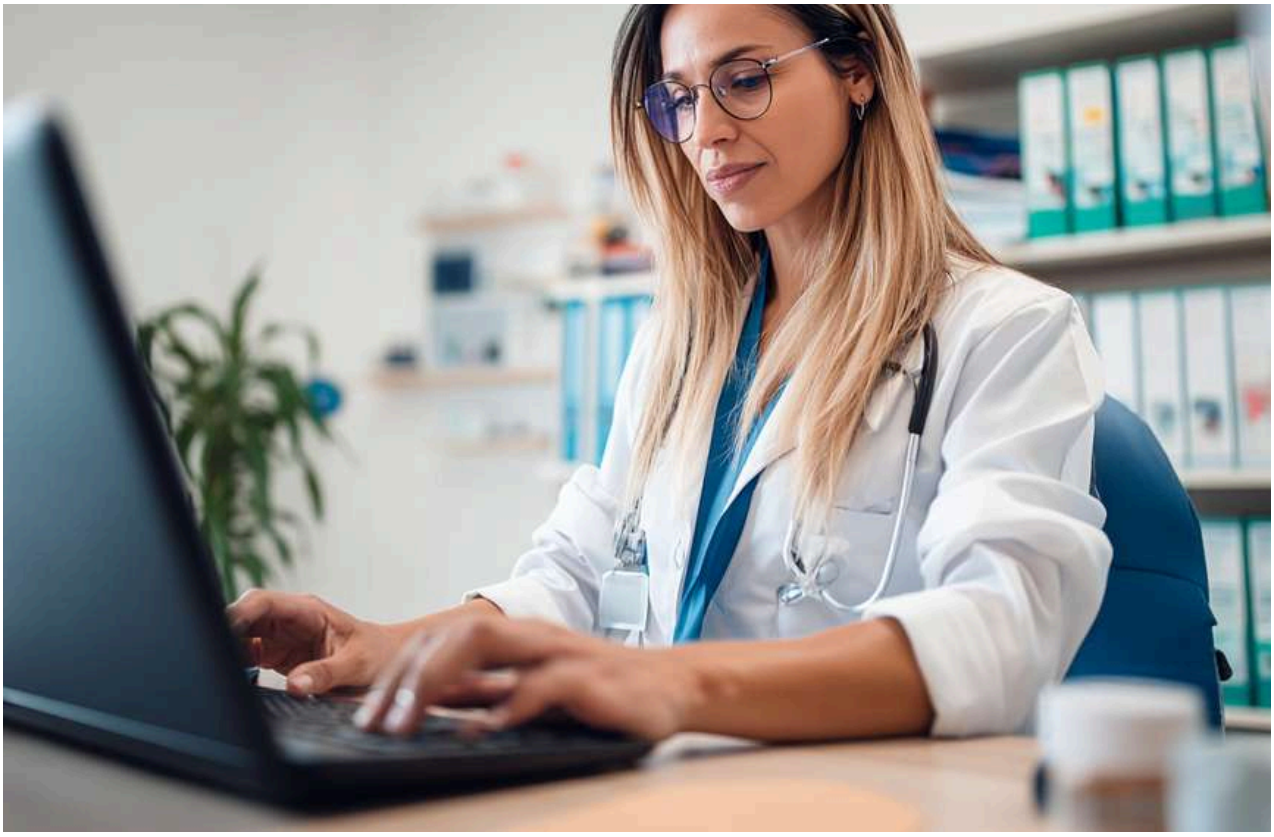
Another initiative involves mapping with the IMDRF (International Medical Device Regulators Forum) system, which has developed a harmonized terminology for reporting adverse events related to medical devices. Specifically, Annex E, containing terms and codes relating to health effects, clinical signs, and symptoms, has been mapped to MedDRA. This mapping is the result of a collaboration between IMDRF and ICH and is available on the IMDRF website.

HOW TO UPDATES YOUR PHARMACOVIGILANCE DATABASE TO THE NEW MEDDRA 28.0 VERSION

Every new version of MedDRA must be incorporated into the pharmacovigilance database. Max Application offers a free service for uploading the new release into SafetyDrugs, the pharmacovigilance safety database. In this way, the pharmacovigilance team can immediately operate with updated terminology, without having to manage technical activities or incur regulatory misalignments. In the daily practice of pharmacovigilance, accurate coding and an always updated dictionary are key elements for identifying signals, drafting reliable reports and maintaining regulatory compliance.

MEDDRA 28.1: WHAT'S NEW FOR PHARMACOVIGILANCE FROM TERMINOLOGY TO THE DESKTOP BROWSER

IN SEPTEMBER 2025, MEDDRA VERSION 28.1 WAS RELEASED, THE GLOBAL MEDICAL-REGULATORY DICTIONARY USED FOR ADVERSE EVENT CODING AND SAFETY DATA ANALYSIS. THE SEMI-ANNUAL UPDATE, IMPLEMENTED ON 3 NOVEMBER 2025, CONSOLIDATES TERMINOLOGY AT THE PT AND LLT LEVELS, EXPANDS LANGUAGE AVAILABILITY, AND INTRODUCES A REDESIGNED DESKTOP BROWSER, WITH DIRECT IMPACTS ON CODING, STANDARDISED QUERIES, AND HISTORICAL DATA COMPARABILITY.



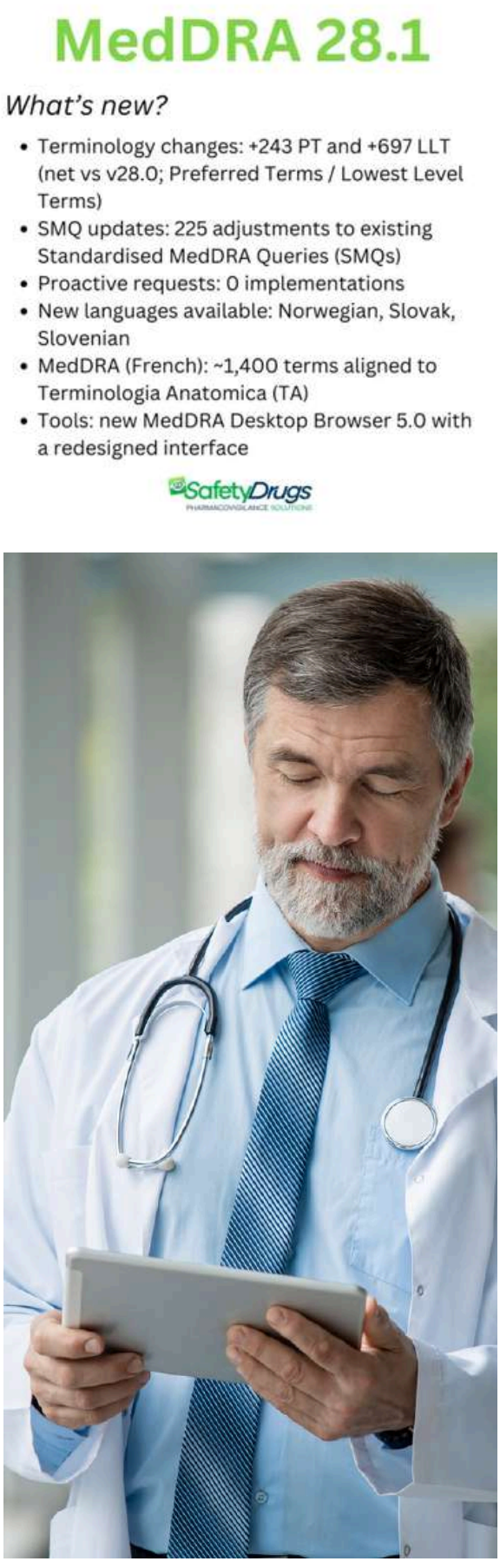
AT A GLANCE: WHAT'S NEW IN MEDDRA 28.1

Version 28.1, as mentioned in the official document What's New MedDRA Version 28.1, is a simple change version: updates apply to PT and LLT only, with no changes at higher levels. Versus 28.0 there is a net increase of +243 PT and +697 LLT (90,471 LLT in total, 81,143 current). SMQs do not increase in count but receive 225 adjustments to their component PTs; totals remain 110 Level-1 topics and 230 including associated sub-SMQs. On languages, Norwegian, Slovak and Slovenian bring availability to 27 languages overall, and the French translation is aligned to the Terminologia Anatomica, the international standard for anatomical terminology, with about 1,400 terms updated. Among tools, the MedDRA Desktop Browser 5.0 debuts with a redesigned interface and consolidated settings. No proactive requests were implemented in this cycle.

WHAT CHANGES IN 28.1 FOR PHARMACOVIGILANCE

Version 28.1 is a "simple change version": changes affect only PT and LLT, with no updates to higher levels. A total of 1.412 change requests were considered; 1.032 were approved, 367 not approved, and 13 remain pending. To analyse differences between versions and assess promotions/demotions of terms, users can rely on the MedDRA Version Analysis Tool (MVAT), which provides results aligned with the Version Report included in the distribution package. Between releases, weekly supplemental updates in English are available and can be consulted via the Web Browser or MVAT.

Quantitatively, total LLTs increase to 90.471, with 81.143 current terms.



SMQ: UPDATES WITHOUT NEW QUERIES

No new SMQs were introduced in 28.1. There were 225 approved changes to PTs within existing SMQs. With the publication of MedDRA 28.1 there are 110 Level-1 SMQ topics (i.e., main topics), for a total of 230 SMQs including the sub-SMQs associated with Level-1 SMQs.

PROACTIVE REQUEST

MedDRA's proactive maintenance allows users to propose cross-cutting interventions to correct inconsistencies and improve terminological coherence and quality outside the standard change-request flow. In the cycle leading to 28.1, no proactive proposals were implemented; the MSSO nevertheless keeps a public list of proposals received and their status in the Change Requests section of the MedDRA website, and invites the community to submit substantiated suggestions to the Help Desk, clearly indicating scope and regulatory/clinical justification. This channel remains essential for user-driven evolution of the terminology, even in a consolidation release like 28.1.

TERMINOLOGIA ANATOMICA IN FRENCH: BROAD ALIGNMENT

The French translation receives an alignment to the Terminologia Anatomica, with approximately 1,400 terms updated. Examples include "Fracture de la rotule" updated to "Fracture de la patella"; the full list appears in the Version Report. This alignment improves precision and uniformity for French-language users.

LANGUAGES: MEDDRA AVAILABLE IN 27 VERSIONS

Version 28.1 adds Norwegian, Slovak, and Slovenian, bringing the total number of available languages to 27. Bulgarian, Danish, Maltese, and Romanian translations are in development; ICH has approved the start of the Uzbek translation.

MEDDRA DESKTOP BROWSER 5.0: WHAT'S GENUINELY NEW

In July 2025, the MSSO released the MedDRA Desktop Browser (MDB) 5.0 with a refreshed design and an interface aligned to the Web-Based Browser introduced in December 2024. The stated goal is to simplify the user experience and place search functionality by far the most frequently used at the centre. All functions from previous versions remain available, with a consolidated settings menu that allows users to tailor the application's behaviour to operational needs. The new MDB 5.0 can be downloaded from the MedDRA website's Download area (login required; a Self-Service Application is available to obtain credentials). The MDB 4.1 app remains available on the MedDRA site. The MSSO Help Desk is available for support.

HOW TO UPDATE THE PHARMACOVIGILANCE DATABASE TO MEDDRA 28.1

Each new MedDRA release must be incorporated into the pharmacovigilance database to ensure coding consistency, comparable analyses, and regulatory compliance. Max Application has installed MedDRA 28.1 on customers' SafetyDrugs databases and continues to offer a free service to load new versions. This ensures that terminology is kept current without technical burden, reducing the risk of misalignment between systems and documentation.

AFI SYMPOSIUM 2025: AGENDA, KEY TOPICS AND A FOCUS ON PHARMACOVIGILANCE

FROM JUNE 11 TO 13, THE RIMINI PALACONGRESSI IN ITALY WILL HOST THE 64TH AFI SYMPOSIUM: A COMPLETE OVERVIEW OF THE SCHEDULED SESSIONS, WITH A SPECIAL FOCUS ON EDUCATIONAL MATERIALS IN PHARMACOVIGILANCE.

The annual AFI Symposium returns this year for its 64th edition. From June 11 to 13, 2025, the Rimini Palacongressi will once again welcome pharmaceutical professionals, companies, regulatory authorities, and service providers for three days of updates, dialogue, and networking. For over sixty years, the event has been a key opportunity to follow the regulatory, scientific, and technological developments that shape the pharmaceutical value chain.

WHAT IS THE AFI SYMPOSIUM?

The AFI Symposium, organized by the Associazione Farmaceutici Industria, is one of the most important scientific and industrial events in the Italian pharmaceutical landscape.

For more than six decades, it has brought together over a thousand participants and offers a rich program of scientific sessions and workshops, alongside a large exhibition area where companies and professionals showcase cutting-edge solutions and technologies.

This year's edition will take place from June 11 to 13, 2025, again at the Rimini Palacongressi. The central theme is: From knowledge to digitalization for a competitive healthcare industry.

AFI SYMPOSIUM 2025: THE PROGRAM

The Symposium agenda includes 18 scientific sessions over three days. The topics range from sustainability to digitalization, medical devices to clinical research, with a strong focus on regulatory affairs and pharmacovigilance.

Wednesday, June 11
3:15 PM to 6:45 PM

- Session I – Energy and Sustainability
- Session II – Innovation (Industry 5.0)
- Session III – Clinical Research

Thursday, June 12

- Session IV: HTA
- Session V: Regulatory Affairs
- Session VI: Quality
- Session VII: Biotech
- Session VIII: Special Productions
- Session IX: PVV – Value Based Healthcare
- Session X: Medical Devices
- Session XI: Supply Chain
- Session XII: Pharmacovigilance
- Session XIII: Pharmaceutical Sciences
- Session XIV: CRS-SITELF

Friday, June 13

- Session XV: Manufacturing
- Session XVI: Digital Health
- Session XVII: Raw Materials
- Session XVIII: Social Trends in the Pharmaceutical Supply Chain

SPOTLIGHT ON THE PHARMACOVIGILANCE SESSION

One of the most anticipated moments of the second day is Session XII – Pharmacovigilance, titled:
"Educational Materials: Managing Effectively in the Digital Age."

Scheduled for Thursday, June 12, from 2:30 to 4:30 PM, in Sala del Castello 2, the session will focus on the evolution of additional risk minimisation measures (aRMMs), following the update of GVP Module XVI and the ongoing transformation in risk communication methods and channels.

An AFI working group on pharmacovigilance has developed a project analysing the Italian landscape and proposing ways to improve the effectiveness of educational materials targeting both healthcare professionals (prescribers and dispensers) and patients.

Speakers will include representatives from AIFA, patient associations, healthcare professional organizations, and industry experts, with contributions from Farmindustria and Egualia.
The session will conclude with an open roundtable discussion, allowing attendees to ask questions and interact directly with the panel.

SAFETYDRUGS AMONG THE EXHIBITORS

Once again, SafetyDrugs will be among the official exhibitors at the AFI Symposium. You can find us at stand 145, ready to welcome those interested in learning more about SafetyDrugs, our pharmacovigilance database, and its integrated Business Intelligence module.
We look forward to meeting professionals and colleagues to share insights, strengthen collaborations, and stay aligned with the latest developments in drug safety.

EUROPEAN PHARMACOVIGILANCE CONGRESS 2025: WHAT TO EXPECT FROM THE EVENT

THE EUROPEAN PHARMACOVIGILANCE CONGRESS IS BACK, ONE OF THE KEY INTERNATIONAL EVENTS DEDICATED TO DRUG SAFETY SURVEILLANCE. HERE'S WHY WE'VE CHOSEN TO TAKE PART AGAIN THIS YEAR.

Scheduled from 19 to 28 November 2025, the European Pharmacovigilance Congress will take place in a hybrid format: two virtual days, 19 and 20 November, and one in-person day in Milan on 28 November, preceded by a networking evening and workshops on 27 November.

Organised by Pharma Education Center, the congress is recognised as one of the main international reference points for professionals working in drug safety, thanks to the high scientific quality of its content, the presence of leading experts, and a practice-oriented approach.

THE PROGRAMME: KEY TOPICS FOR THOSE WORKING IN DRUG SAFETY

The European Pharmacovigilance Congress provides a valuable opportunity to discuss core aspects of pharmacovigilance operations. The 2025 programme offers a clear reflection of today's priorities.

19 November (online)

09:00 – 09:15 Welcome and opening of the conference
09:20 – 11:00 Advancing signal detection in pharmacovigilance: modern methodologies and best practices
11:00 – 11:20 Coffee break and networking
11:20 – 12:40 Risk management e, in parallelo, Safety of combination products
12:40 – 13:45 Lunch and networking
13:45 – 15:20 Importance of real-world data sources and evidence beyond spontaneous reporting e, in parallel, Cosmetovigilance
15:20 – 15:40 Coffee break
15:40 – 17:20 Patients' representatives' contribution to pharmacovigilance e, in parallelo, Non EU pharmacovigilance requirements
17:20 – 17:25 Lectio magistralis

20 November (online)

09:00 – 09:10 Welcome and opening of the conference
09:10 – 10:45 Authorities review of pharmacovigilance data from clinical development to when things go wrong
10:45 – 11:05 Coffe break
11:05 – 12:40 Benefit/risk evaluation of medicinal products e, in parallelo Labelling: a fundamental risk communication and minimization tool
12:40 – 13:45 Pausa pranzo
13:45 – 15:20 Regulatory aspects for implementing Artificial Intelligence in pharmacovigilance e, in parallelo, Aggregate reports around the world
15:20 – 15:40 Coffee break
15:40 – 17:20 Immunologically driven adverse reactions e, in parallelo, Practical examples of Artificial Intelligence implementation in pharmacovigilance processes

28 November (in person, Milan)

08:30 – 09:30 Registration of attendees, welcome and opening of the conference
09:30 – 11:00 Overcoming challenges and prioritizing value in the evolving pharmacovigilance landscape
11:00 – 11:30 Coffee break and networking
11:30 – 13:00 Personalized pharmacovigilance e in parallelo, Workshop Pharmacovigilance in transition: adapting to global and regional regulatory change
13:15 – 14:15 Lunch and networking
14:15 – 15:20 PRAC and other European authority processes for monitoring the benefit-risk of drugs e, in parallelo, New skills needed in pharmacovigilance
15:20 – 15:45 Coffee break and networking
15:45 – 17:40 Pre & post marketing audits & inspections

NETWORKING OPPORTUNITIES

This year's edition will feature over 70 speakers, more than 400 attendees and 14 sponsors, including SafetyDrugs. We'll be there to meet professionals in the field, discuss emerging challenges in drug safety management, and showcase our solution for post-marketing surveillance, a tool to support complex operations, ensure traceability, structure, and compliance, and help teams manage everyday tasks with greater confidence.

If you're attending the congress, we invite you to stop by our stand. It will be a chance to explore how SafetyDrugs works and exchange ideas on how to keep improving pharmacovigilance processes.

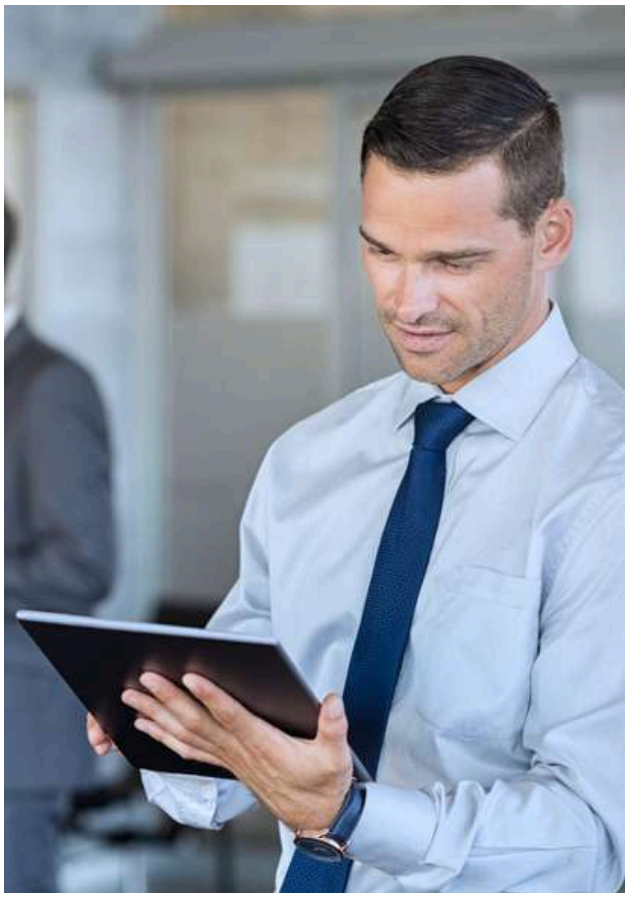
PHARMACOVIGILANCE AND DATA SECURITY: WHY WE CHOSE ISO 27001 CERTIFICATION

DATA PROTECTION IN PHARMACOVIGILANCE DEMANDS HIGH STANDARDS AND ONGOING COMMITMENT. IN THIS ARTICLE, WE EXPLAIN WHY WE DECIDED TO CERTIFY OUR SYSTEMS WITH ISO 27001 AND WHAT IT MEANS TO WORK WITH A PARTNER THAT ADOPTS A STRUCTURED APPROACH TO INFORMATION SECURITY.

WHY ISO 27001 MATTERS IN PHARMACOVIGILANCE

Anyone working in pharmacovigilance knows that data is more than just information—it's a responsibility. Protecting it is not just a technical duty; it's a fundamental requirement for operating ethically, compliantly, and sustainably.

With this shared awareness, Max Application, provider of SafetyDrugs, the database used for pharmacovigilance management, chose to go a step further: to become ISO 27001 certified. This decision was made to better meet our clients' needs for security and reliability, and it was accompanied by a series of organizational and operational improvements.



WHAT ISO 27001 IS AND WHY IT MATTERS TO YOU

ISO 27001 is the world's most recognized standard for information security management. Published by the International Organization for Standardization (ISO), it outlines the requirements for establishing, implementing, maintaining, and continuously improving an Information Security Management System (ISMS).

This system includes policies, procedures, resources, and tools to protect information from unauthorized access, loss, theft, or compromise. It applies not only to technology, but also to people, governance, and company culture.

Organizations that achieve ISO 27001 certification demonstrate that they have systematically assessed their information risks and implemented appropriate measures to manage them. The standard also requires senior management involvement, staff training, and continuous monitoring of all critical processes.

Today, information security is increasingly vital for those working in regulatory and pharmaceutical fields. ISO 27001 certification offers internationally recognized assurance that an organization has adopted a structured and measurable approach to data protection.

TRUST DOESN'T HAPPEN BY CHANCE

Max Application has always operated in highly secure environments, thanks in part to the Oracle data centers where pharmacovigilance data is hosted. However, ISO 27001 certification adds another layer. It's not just about where the data resides—it's about how it is managed daily. The responsibility for data security is a constant collaboration between us and our technology partners.

This certification, issued by the independent body Certiquality, confirms that Max Application has implemented an Information Security Management System that can:

- ensure the confidentiality of sensitive and strategic data;
- guarantee business continuity, even in critical situations;
- maintain data traceability and integrity to comply with regulatory obligations;
- continuously and systematically adapt to technological and regulatory changes.

In pharmacovigilance, where every piece of information can make a difference, this approach isn't just useful, it's essential.

WHAT IT MEANS TO HAVE A TECHNOLOGY PARTNER CERTIFIED IN ISO 27001

For those involved in pharmacovigilance, it's essential to ensure that every report, every piece of data, and every submission is complete, verifiable, and ready for regulatory authorities—and always available for audits or inspections.

Working with an ISO 27001 certified partner means relying on data management that is structured, transparent, and aligned with international standards:

- your data is hosted in controlled environments that follow best security practices;
- proven procedures are in place to prevent and promptly address any critical issues;
- you can count on a partner who has integrated security into its daily operations, with the goal of protecting, informing, and supporting pharmacovigilance professionals.

SECURITY AS A PROCESS, NOT A RESULT

ISO 27001 is not a final goal. It is a commitment: to constantly improve processes, stay updated on new security technologies, anticipate threats, and align with evolving regulatory requirements. We will continue to invest in what truly matters: the security of your data and the peace of mind in your daily work.

LILT BIELLA'S ALVEARE AMICO: THE SPACE FOR CHILDREN WITH CANCER HAS BEEN OFFICIALLY INAUGURATED THANKS TO THE PIGIAMA RUN

WE'VE SEEN WITH OUR OWN EYES WHAT SOLIDARITY CAN BRING: LILT BIELLA'S ALVEARE AMICO SPACE FOR CHILDREN WITH CANCER IS FINALLY A REALITY. HERE'S HOW THE INAUGURATION WENT AND WHY IT WAS A SPECIAL MOMENT FOR US.

LILT Biella's new Alveare Amico space for children with cancer was officially inaugurated on June 4th. A safe and welcoming environment, designed to meet the concrete needs of those facing a difficult journey. A project born to offer concrete support to local families and made possible thanks to the Pigiama Run Biella, the charity race we have supported for two years as a sponsor and with the participation of our team. Seeing the tangible results achieved has confirmed the profound value of this charitable initiative.

ALVEARE AMICO: A CONCRETE PROJECY BORN FROM REAL NEEDS

The Alveare Amico project was born from careful and participatory listening: that of LILT Biella towards local families with children and adolescents suffering from oncology. The families benefiting from the project – residents in the province of Biella – often have to travel to specialist centers outside the region. This causes financial, emotional, and organizational hardship, compounded by the fragility of the disease.

LILT Biella responded to these difficulties by creating a welcoming, informal, and functional environment within the LILT Space. The name itself evokes the idea of the beehive as a symbol of industriousness, cooperation, and mutual support: values that form the basis of a strong and supportive community. Like bees, every gesture contributes to the well-being of the entire ecosystem.

THE INAUGURATION: AN AFTERNOON OF EMOTION AND SHARING

The inauguration of Alveare Amico opened under a light rain. LILT Biella director Rita Levis kicked off the event with a heartfelt speech, explaining the idea behind the project: like in a beehive, each bee works together and no one is left behind.

A message that resonated strongly in the hearts of everyone in attendance.

Next came the most symbolic moment: the ribbon-cutting ceremony, performed by the director alongside two children.

A simple yet meaningful gesture, it marked the official opening of the area.

The inaugurated space consists of two rooms.

In the first, dedicated to families, a welcoming atmosphere immediately emerges: a large table, a sofa, thoughtful furnishings, and a wall completely decorated with a large beehive, where each hexagon represents a donation received.

The second room is designed for children: custom-sized tables, bookcases, stuffed animals, games, and a wall with delicate and colorful floral illustrations. The entire decor plays on shades of yellow, green, and blue, with a sober yet playful elegance, maintaining balance and aesthetic care.

The atmosphere was that of a true celebration. We felt a profound sense of shared emotion, gratitude, and satisfaction for something we had built together.

PIGIAMA RUN 2025: JOIN US!

We are proud to have contributed to the creation of Alveare Amico and to once again support the Pigiama Run Biella.

The next edition is scheduled for September 26, 2025: we'll run again, in our pajamas, to bring hope, support, and concrete help to children who face the most difficult challenges every day. Join us!

Find out how to participate in the next edition on the official website pigiamarun.it.

Together, we can make a difference.

"Like in a beehive, no bee is left alone."

PIGIAMA RUN 2025: RUNNING FOR PEDIATRIC CANCER AWARENESS

EVERY YEAR, THOUSANDS OF CHILDREN AND ADOLESCENTS ARE DIAGNOSED WITH CANCER. SEPTEMBER IS DEDICATED TO RAISING AWARENESS, AND PIGIAMA RUN 2025 IS A UNIQUE OPPORTUNITY TO BRING TOGETHER RESEARCH, SOLIDARITY, AND COMMUNITY. IN THIS ARTICLE, WE EXPLAIN WHY THIS EVENT IS SO IMPORTANT AND HOW SAFETYDRUGS IS ACTIVELY TAKING PART IN BIELLA.

PEDIATRIC CANCER: A CHALLENGE THAT CONCERC US ALL

Pediatric cancers are among the most delicate challenges in modern medicine. They affect the youngest patients, often school-age children, and have a profound impact on their families. According to data collected by AIRTUM – the Italian Association of Cancer Registries, every year in Italy an estimated 1,400 new cases are diagnosed in children (ages 0–14) and about 800 in adolescents (ages 15–19).[1].

Behind these figures lie stories of courage, hospitals, and long and demanding therapies. Although scientific progress has significantly improved survival rates, research must continue to develop more effective and less invasive treatments, so that children can fully live their childhood.

This is why it is essential for the scientific community, institutions, and society at large to work together: the fight against pediatric cancer is not only waged in laboratories, but also through awareness and concrete support.
[1] Source: AIRC – Tumori pediatrici

SEPTEMBER, A MONTH DEDICATED TI PEDIATRIC CANCER

September is the international month dedicated to pediatric cancer awareness. A period designed to increase public knowledge of these diseases, support families, and raise funds for research. Solidarity initiatives play a central role: they remind us that illness does not affect only those who experience it firsthand, but the entire community. They offer everyone the chance to contribute, in their own way, to the fight against childhood cancer.

PIGIAMA RUN 2025: RUNNING IN PIJAMAS FOR AWARNESS

It is in this context that Pigiama Run 2025, organized by LILT – the Italian League for the Fight Against Cancer, will take place on Friday, September 26th at 7:00 PM, in over 30 Italian cities.

The heart of the event is its symbol: running or walking in pajamas, the clothing that accompanies young cancer patients through long days of treatment. Wearing pajamas during the run means transforming an everyday garment into an act of closeness and awareness, a way of saying: you are not alone.

FROM RUNNING TO CONCRETE RESULTS: THE BIRTH OF ALVEARE AMICO

The run is not only a moment of awareness: it is also a fundraising tool that supports concrete projects improving the lives of pediatric cancer patients.

The 2024 edition of Pigiama Run Biella, organized by the Biella Provincial Committee of LILT, is a clear example: the extraordinary turnout raised enough funds to create Alveare Amico, a dedicated space within Spazio LILT for children with cancer and their families.

Alveare Amico is more than just a place: it is a welcoming refuge where young patients can find normality, play, psychological support, and dedicated activities. It demonstrates how every run, every registration, and every pajama worn can be transformed into real help that makes a difference in the daily lives of those facing a difficult journey.

PIGIAMA RUN AND SAFETYDRUGS: A COMMITMENT THAT CONTINUES

Biella is also the home of SafetyDrugs, the pharmacovigilance database developed by Max Application. For three years now, we have supported the event as a sponsor and joined hundreds of citizens in running to help raise funds for families of children with cancer.

For SafetyDrugs, renewing its support for Pigiama Run 2025 means continuing a commitment that produces tangible results and strengthens our closeness to patients and their families. This is why we invite everyone to join this important initiative of social value.

HOW TO TAKE PART

Pigiama Run 2025 will be held on Friday, September 26th at 7:00 PM. Each participant can choose whether to run or walk, in person in their city or virtually, wherever they are.

To register and learn more: www.pigiamarun.it

The SafetyDrugs team will be on the front line in Biella, but we hope that more and more people, professionals, and companies will join this initiative, because together we can make a difference in the fight against pediatric cancer.

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