



SD

COLLECTION

2025 SPECIAL

PHARMACOVIGILANCE, MEDICAL DEVICE AND CLINICAL STUDIES

SUMMARY

PHARMACOVIGILANCE

HISTORY OF PHARMACOVIGILANCE: EVOLUTION AND PROGRESS IN DRUG SAFETY SURVEILLANCE	03
PHARMACOVIGILANCE: ANSWERS TO THE FREQUENTLY ASKED QUESTIONS ABOUT DRUG SAFETY	11
PHARMACOVIGILANCE IN 2024: HOW THE EUROPEAN LANDSCAPE IS CHANGING	21
GVP XVI REVIEW: RISK MINIMIZATION UPDATES	23
EUDRAVIGILANCE: UPDATES AND IMPROVEMENTS FOR MORE EFFICIENT MANAGEMENT	25
EMA ACCOUNT MANAGEMENT: NEW FEATURES AND UPDATES FOR EASIER AND MORE SECURE MANAGEMENT	27
ARTIFICIAL INTELLIGENCE AND EMA: INITIATIVES FOR USE IN PHARMACOVIGILANCE	30

SUMMARY

PHARMACOVIGILANCE EVENTS

AFI SYMPOSIUM 2024: NEWS FROM PHARMA FIELD 34

EU PHV CONGRESS 2024: AN EVENT NOT TO BE MISSED 45

NEWS FROM PHARMA

AIFA REFORM: WHAT IS AND WHO ARE THE NEW MEMBERS OF THE BOARD 47

PHARMACOVIGILANCE: NEW FUNDS EXPECTED FROM AIFA'S BOARD OF DIRECTORS 52

AIFA LAUNCHES A NEW DIGITAL PLATFORM FOR THE MANAGEMENT OF PHARMACOVIGILANCE FUNDS 53

CLINICAL TRIALS

CLINICAL TRIALS: WHAT THEY ARE? 55

MEDICAL DEVICES

MEDICAL DEVICES: WHAT DOES IT CHANGE WITH THE AI ACT? 69

CORPORATE EVENT

RALLY LANA 2024 75

PIGIAMA RUN 2024: JOIN US FOR LILT'S CHARITY RUN 78

HISTORY OF PHARMACOVIGILANCE: EVOLUTION AND PROGRESS

PHARMACOVIGILANCE WAS OFFICIALLY BORN IN 1961 IN GREAT BRITAIN FOLLOWING THE SERIOUS ADVERSE EVENTS CAUSED BY THE ADMINISTRATION OF THALIDOMIDE TO PREGNANT WOMEN. HOWEVER, NUMEROUS EVENTS HAVE MARKED THE HISTORY OF PHARMACOVIGILANCE. HERE IS ITS EVOLUTION, FROM ITS ORIGIN IN 1848 WITH THE USE OF CHLOROFORM, TO ITS CURRENT FORM.

WHAT IS PHARMACOVIGILANCE?

The term pharmacovigilance derives from the Greek and Latin words pharmakon, meaning medicinal substance, and vigila, meaning to watch. Pharmacovigilance, according to the World Health Organization (WHO), is “the discipline and set of activities aimed at the identification, evaluation and prevention of adverse effects or other problems related to the use of medicines”. It is therefore a fundamental activity to guarantee the safety profile of a drug.



WHEN WAS PHARMACOVIGILANCE BORN?

Pharmacovigilance was born in 1961 in Great Britain, when, following the administration of Thalidomide to pregnant women, numerous episodes of fetal malformations occurred. This crucial event marked the start of drug surveillance activity, but there were numerous cases of previous suspected reactions that led to this activity as we know it today. The first occurred in 1848.

HISTORY OF PHARMACOVIGILANCE: KEY EVENTS

Over the years there have been various events that have led to the establishment of modern pharmacovigilance. Here they are below.

1848 - Chloroform

The history of pharmacovigilance dates back to 1848, when a series of suspicious deaths occurred in Great Britain during operations in which chloroform was administered to patients as an anesthetic. Chloroform was used as an anesthetic starting in 1847. The following year a 15-year-old girl died following its use. This tragic event sparked concern, prompting the Lancet Journal to set up a commission and urge British doctors to report similar cases. A debate therefore opened on the safety of anesthetic procedures and following various reports, the drug ceased to be used as an anesthetic in 1876. This episode represented the first step towards the establishment of pharmacological safety procedures.

1937 - Sulfanilamide

Another turning point occurred in the United States in 1937, when 107 people, including 76 newborns, lost their lives due to a new liquid formulation of Sulfanilamide containing the solvent Diethylglycol as a diluent, which caused fatal reactions. Currently, this component is known for its high toxicity and is used as an antifreeze liquid in car engines. This tragedy highlighted the importance of ensuring the safety not only of the active ingredient, but also of the excipients that make up the drug.



1961 - Thalidomide

The decisive event for the birth of pharmacovigilance occurred in 1961 when the use of Thalidomide during pregnancy caused a 20% increase in congenital malformations in newborns. The drug was tested for two years on 300 patients, without detecting any particular side effects. Therefore, considered safe, it was marketed in over 50 countries starting from 1957. Thalidomide was used primarily as a sedative, antiemetic and hypnotic in pregnant women. Its administration caused a serious anomaly in the development of the fetus: the newborns had serious deformities of the limbs, especially the upper ones, such as the absence (amelia) or reduction of the bones (phocomelia). Approximately 10,000 to 20,000 children suffered incomplete development.

In 1961, reports on possible correlations between Thalidomide and congenital malformations were published in the scientific journal Lancet. The turning point came with the letter from Doctor William Griffith McBride in December of the same year, in which he suggested a connection between congenital malformations and the intake of the drug and making public the first cases of fetal abnormalities linked to Thalidomide. This can be considered as the beginning of spontaneous reports. The hypothesis of the correlation between the malformations and the intake of the drug was therefore consolidated, and it was withdrawn from the market. This event in the history of pharmacovigilance marked the transition from an occasional activity to a systematic, organized and regulated process.



BIRTH OF THE BODIES

Following these events, the first bodies and procedures emerged aimed at monitoring the safety of the drug.

In 1938 the Food, Drug and Cosmetic Act (FFDCA, FDCA, or FD&C) was established in the United States, a set of laws to charge the Food and Drug Administration (FDA) (established in 1906) with supervising the safety of foods, drugs, medical devices and cosmetics, laying the foundations of pharmaceutical legislation.

In 1948, the World Health Organization (WHO) was founded in Geneva to centralize health issues worldwide.

In 1962, following the Thalidomide accident, the Harris-Kefauver amendments were introduced in the United States, which mandated the

need to conduct mandatory preclinical studies. Only after the evaluation of the results of these studies was it possible to start the clinical trial phase on humans. Furthermore, the marketing authorization depended on the data obtained in the three phases of the clinical trial. After marketing, the drugs were subjected to post-marketing surveillance.

In the United Kingdom, the Yellow Card, the first form for reporting adverse reactions by doctors, was introduced in 1964.

The WHO, in 1968, promoted the Program on International Drug Monitoring (PIDM), an international drug monitoring program aimed at centralizing global data on adverse reactions. 10 states were initially involved: Australia, Canada, Czechoslovakia, Ireland, the Netherlands, Germany, New Zealand,



Sweden, the United Kingdom, the USA (Italy joined in 1975). The program was immediately effective: the following year it emerged that Clioquinol, an antimycotic drug, caused retrobulbar optic neuritis in Asian countries, revealing an ethnic susceptibility to the drugs and their adverse effects.

Furthermore, in 1971 it emerged that diethylstilbestrol, an estrogen of synthetic origin, which had been administered since the 1940s to pregnant women to prevent spontaneous abortions and to relieve nausea, caused genital tumors in the daughters of women exposed to this substance during pregnancy.

For pharmacovigilance it meant learning that adverse drug effects can occur years later or even in the next generation. In that same year, WHO created the global reporting database located in Uppsala, Sweden.

In 1973, France inaugurated the first six hospital surveillance centers, where the term pharmacovigilance was formally adopted.

The Swedish government and the WHO founded the Uppsala monitoring center in 1978.

In 1995, the European Medicines Agency (EMA) was founded. In 2001, Eudravigilance, the European database for the management of reports, was implemented.

In Italy, the National Pharmacovigilance Network (RNF) was created in 2001 to collect reports of adverse reactions at a national level and in 2003 the Italian Medicines Agency (AIFA) was created. As proof of the growing awareness at a national level, some collaborative groups

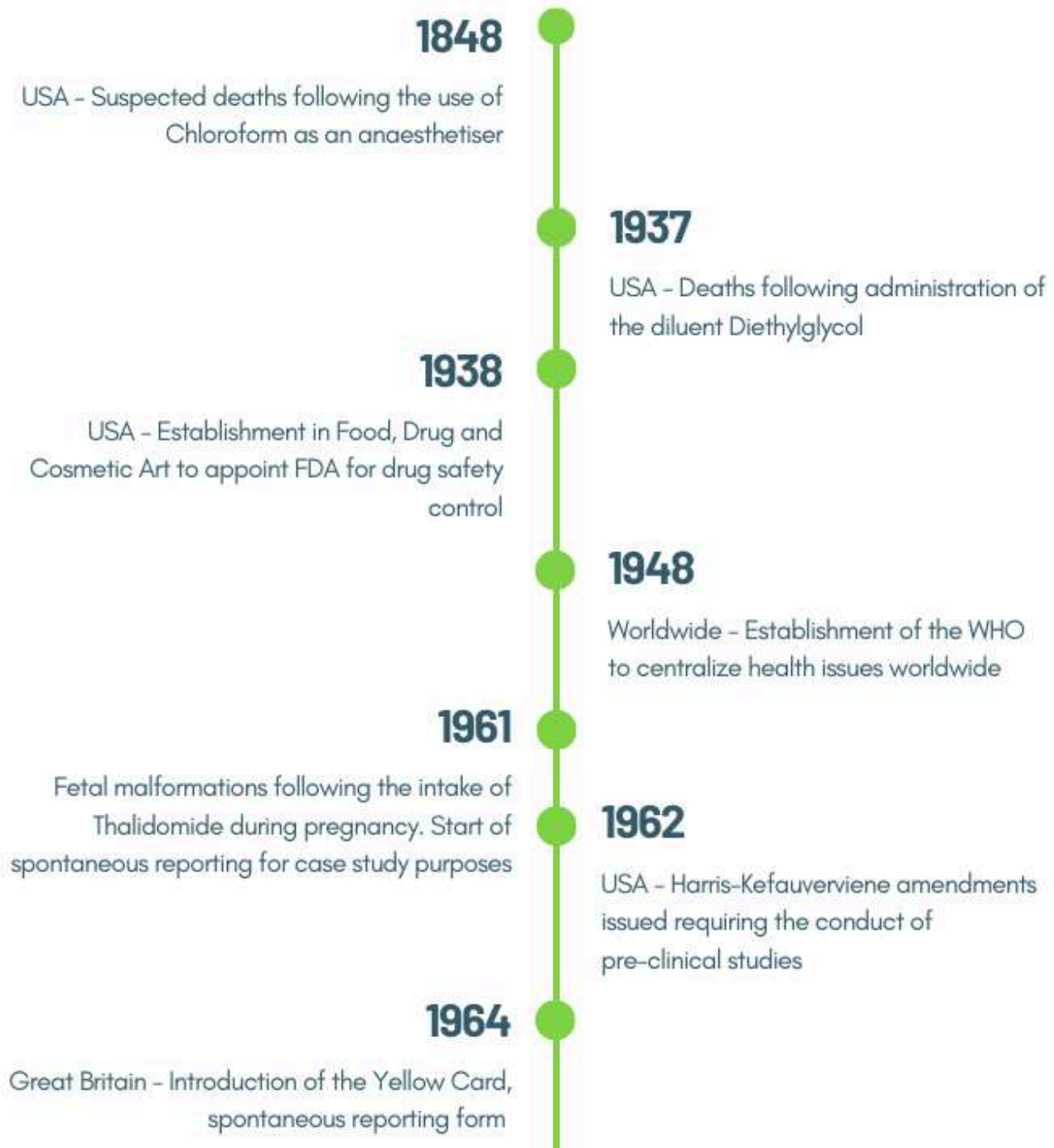
were established such as the Interregional Pharmacovigilance Group (GIF) and the Italian Group for Epidemiological Studies in Dermatology (GISED). Furthermore, since 2006, Italian healthcare companies have been obliged to designate a qualified person as responsible for pharmacovigilance activities (QPPV).

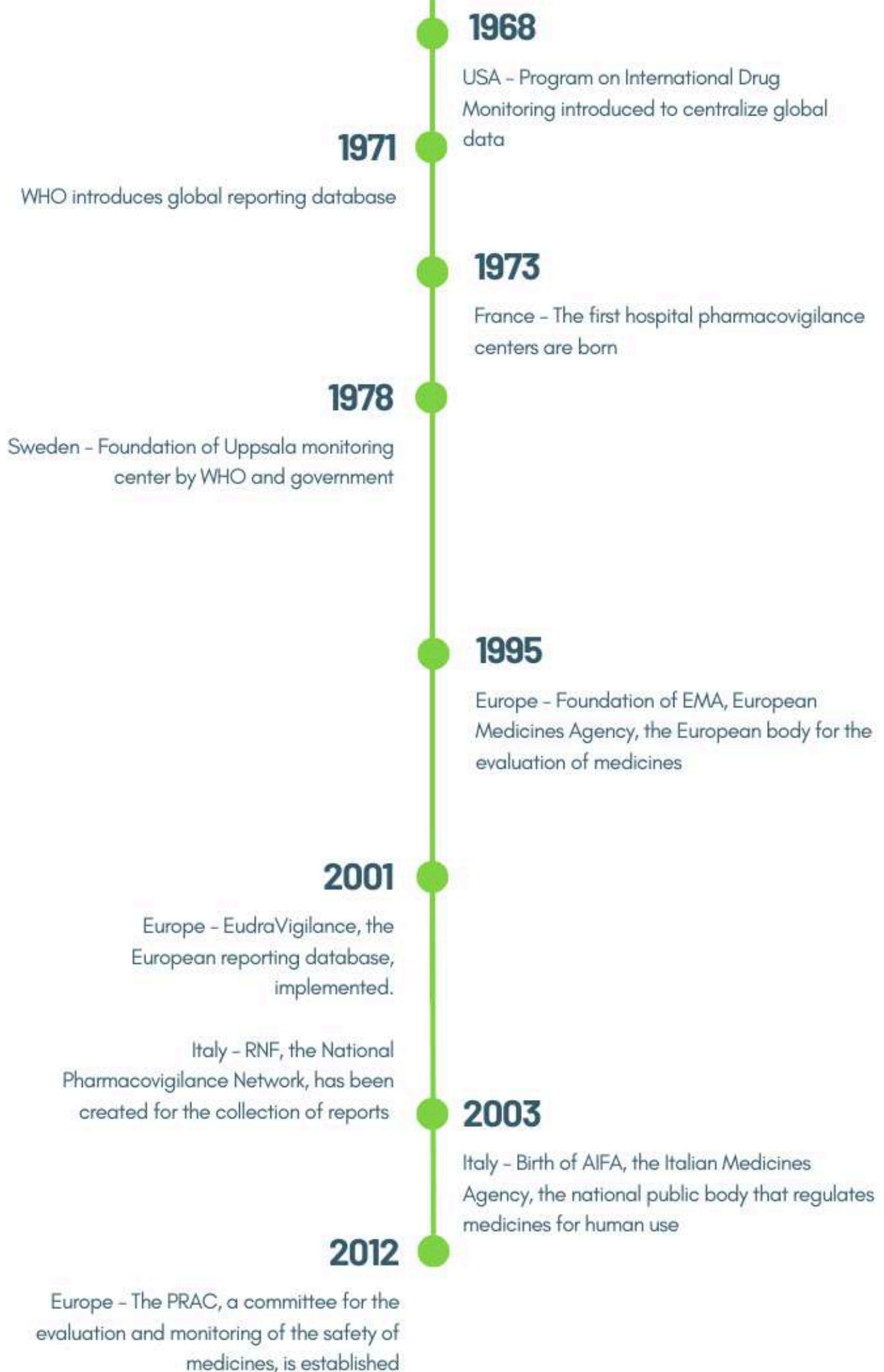
With the establishment of the Pharmacovigilance Risk Assessment Committee (PRAC) in 2012, the European pharmacovigilance system was further strengthened, clearly defining roles and responsibilities. The PRAC is responsible for evaluating and monitoring the safety of medicines for human use, providing recommendations to the relevant committees.



HISTORY OF

PHARMACOVIGILANCE







THE CURRENT SCENARIO

Pharmacovigilance has made significant progress, moving from a passive monitoring system that relied exclusively on spontaneous reporting of suspected adverse reactions to a more proactive approach. The latter makes use of targeted tools and procedures which include detailed risk monitoring planning (Risk Management Plan). Pharmacovigilance regulations have played a key role in regulating the activities of the various figures involved and recent legislative updates have broadened the definition of adverse reactions to include medication errors, abuses and overdoses, thus leading to an increase in reporting. European regulations now also require greater timeliness in reporting.

The evolution of pharmacovigilance has been made possible above all thanks to the improvement of both the quantity and quality of spontaneous reports, actively involving professionals and patients. Furthermore, activities aimed at refining signal search methods and improving communication with healthcare professionals were conducted. Pharmacovigilance systems around the world are undergoing significant changes in line with technological progress, such as the transition to ICH E2B (R3), the recent electronic reporting format – Individual Case Safety Report (ICSR). An essential help for all operators involved in pharmacovigilance processes is to equip themselves with a safety database developed in compliance with the most recent regulatory requirements.

PHARMACOVIGILANCE: ANSWERS TO THE FREQUENTLY ASKED QUESTIONS ABOUT DRUG SAFETY

PHARMACOVIGILANCE IS A FUNDAMENTAL ACTIVITY TO ENSURE DRUG SAFETY GLOBALLY. SINCE ITS INCEPTION IN THE 1960S, SIGNIFICANT PROGRESS HAS BEEN MADE. HOWEVER, THIS ACTIVITY CONTINUES TO RAISE QUESTIONS AND DOUBTS. IN A CONSTANT EFFORT TO RAISE AWARENESS ABOUT THE IMPORTANCE OF THIS PRACTICE, WE HAVE COLLECTED AND ANSWERED THE FAQs ABOUT PHARMACOVIGILANCE. HERE THEY ARE BELOW.

WHAT IS PHARMACOVIGILANCE?

Pharmacovigilance, according to the World Health Organization, is the scientific discipline dedicated to the collection, assessment, understanding, and prevention of adverse effects related to the use of drugs. This practice not only focuses on identifying side effects but also aims to better understand their impact on public health and to identify any risks associated with drug use. Pharmacovigilance is essential to ensure the effectiveness and safety of drugs, thus contributing to protecting patients' health.

WHEN WAS PHARMACOVIGILANCE BORN?

Pharmacovigilance originated in response to the tragic thalidomide incident that occurred in the 1950s and 1960s. This drug, prescribed as a painkiller and antiemetic for pregnant women, caused severe fetal malformations. This event highlighted the need for closer monitoring of drugs after they are marketed, leading to the establishment of pharmacovigilance.





WHAT IS THE GOAL OF PHARMACOVIGILANCE?

The primary goal of pharmacovigilance is to ensure drug safety and the best risk/benefit ratio to protect public health. This goal is made possible by the constant monitoring of drug tolerability and efficacy, the timely identification of adverse effects, and the adoption of risk minimization measures associated with drug use. For this purpose, the stakeholders analyze data to search for a signal that indicates an unexpected outcome.

WHAT IS A SIGNAL IN PHARMACOVIGILANCE?

In pharmacovigilance, a signal refers to information suggesting an unexpected outcome, such as a new possible association between a drug and an adverse event or an increase in frequency or severity. The emergence of a signal involves further investigations and in-depth evaluations of the drug's effectiveness or associated risks. The research and management of the signal are regulated processes governed by pharmacovigilance regulations and guidelines.

HOW IS A SIGNAL MANAGED IN PHARMACOVIGILANCE?

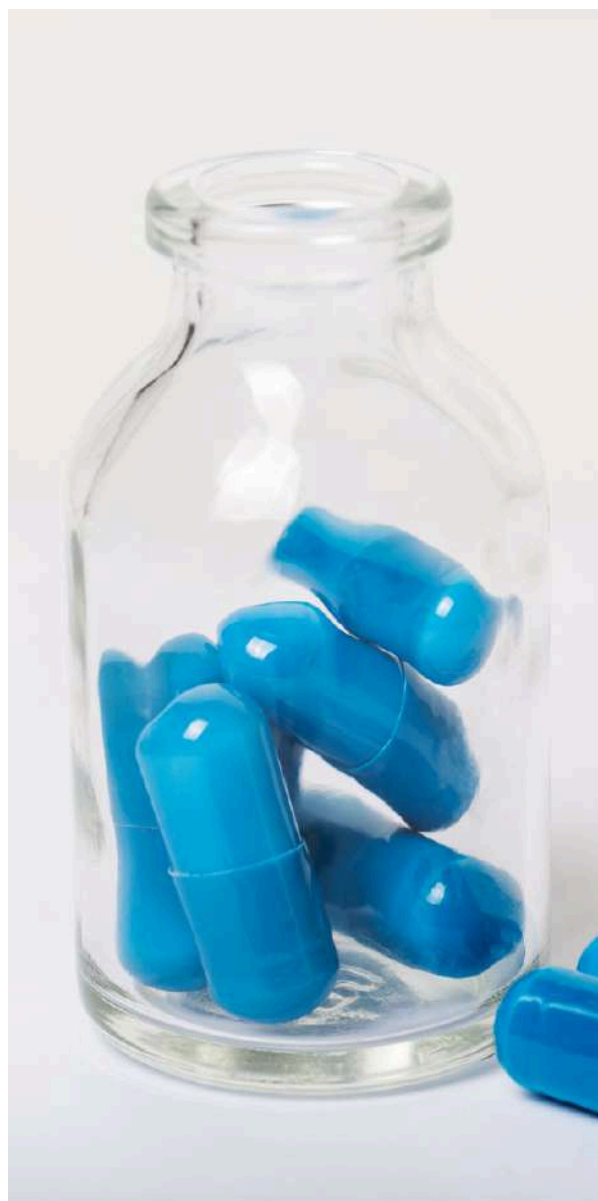
In pharmacovigilance, signal management follows a rigorous process regulated by specific regulations and guidelines. This process consists of several phases:

1. Signal Detection. This phase involves analyzing various relevant sources to identify potential signals of adverse events related to drug use.
2. Signal Validation. Here, the data supporting the identified signal are evaluated to determine if there is a sufficiently documented cause-effect relationship.
3. Signal Analysis and Prioritization. Signals requiring immediate attention are identified, including those posing significant risks to public health or affecting the risk-benefit ratio of a drug.
4. Signal Assessment. An in-depth assessment of the validated signal is conducted to identify any new risks or changes in causal associations with the drug and to determine any necessary regulatory actions.
5. Recommendations for Actions. The need for further actions in response to the signal evaluation results is assessed.
6. Exchange of Information. All parties involved in pharmacovigilance exchange relevant information to ensure effective and timely signal management.

By following this structured approach, accurate assessment and appropriate management of drug safety signals can be ensured.

WHICH DRUG ARE SUBJECT TO PHARMACOVIGILANCE?

All drugs must undergo pharmacovigilance, including newly marketed drugs and those already approved and used. This includes various types of drugs, such as generic drugs, biologics, and over-the-counter drugs. Continuous surveillance is essential to identify and evaluate any adverse reactions or drug safety issues.



WHO IS INVOLVED IN PHARMACOVIGILANCE?

Pharmacovigilance involves various stakeholders working together to ensure drug safety and protect public health.

These include:

- Pharmaceutical companies, responsible for drug marketing and compliance with safety regulations.
- Regulatory authorities such as the World Health Organization (WHO), the European Medicines Agency (EMA), the Italian Medicines Agency (AIFA), and all National Competent Authorities (NCA), overseeing and regulating drug approval, marketing, and monitoring.
- Healthcare professionals, required to report patients' adverse reactions to competent authorities to contribute to drug safety monitoring.
- Patients or caregivers, who can directly report any adverse effects or reactions related to drug use to competent authorities or pharmaceutical companies.

WHAT ARE THE REGULATORY AUTHORITIES' ROLES IN DRUG SAFETY SURVEILLANCE?

There are numerous agencies responsible for pharmacovigilance. Each country has its own national agencies responsible for the approval, regulation, and surveillance of drugs within its territory. For example, in Italy, there is the Italian Medicines Agency (AIFA), in France, there is the National Agency for the Safety of Medicines and Health Products (ANSM), in Spain, there is the Spanish Agency of Medicines and Medical Devices (AEMPS), and so on.

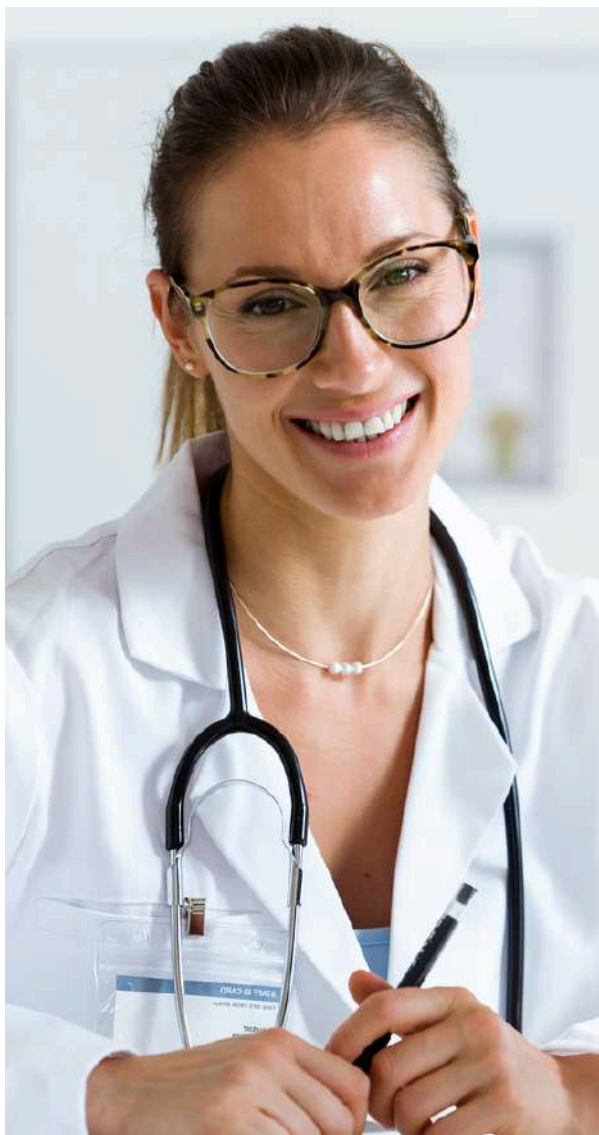
Pharmacovigilance is then coordinated by continental-level entities. In Europe, this responsibility falls on the European Medicines Agency (EMA), which collects, manages, and analyzes reports of suspected adverse drug reactions through the EudraVigilance database. In the United States, drug safety surveillance is managed by the Food and Drug Administration (FDA), which plays a fundamental role in the approval, monitoring, and regulation of drugs marketed in the USA. For example, in Asia, there is the Japanese authority Pharmaceuticals and Medical Devices Agency (PMDA), closely aligned with Western guidelines.

However, pharmacovigilance is centrally coordinated globally by the World Health Organization (WHO), which is committed to monitoring and coordinating drug safety activities on a global scale.



WHAT ARE THE PHARMACEUTICAL COMPANIES' RESPONSIBILITIES MONITORING THE SAFETY OF THEIR PRODUCTS?

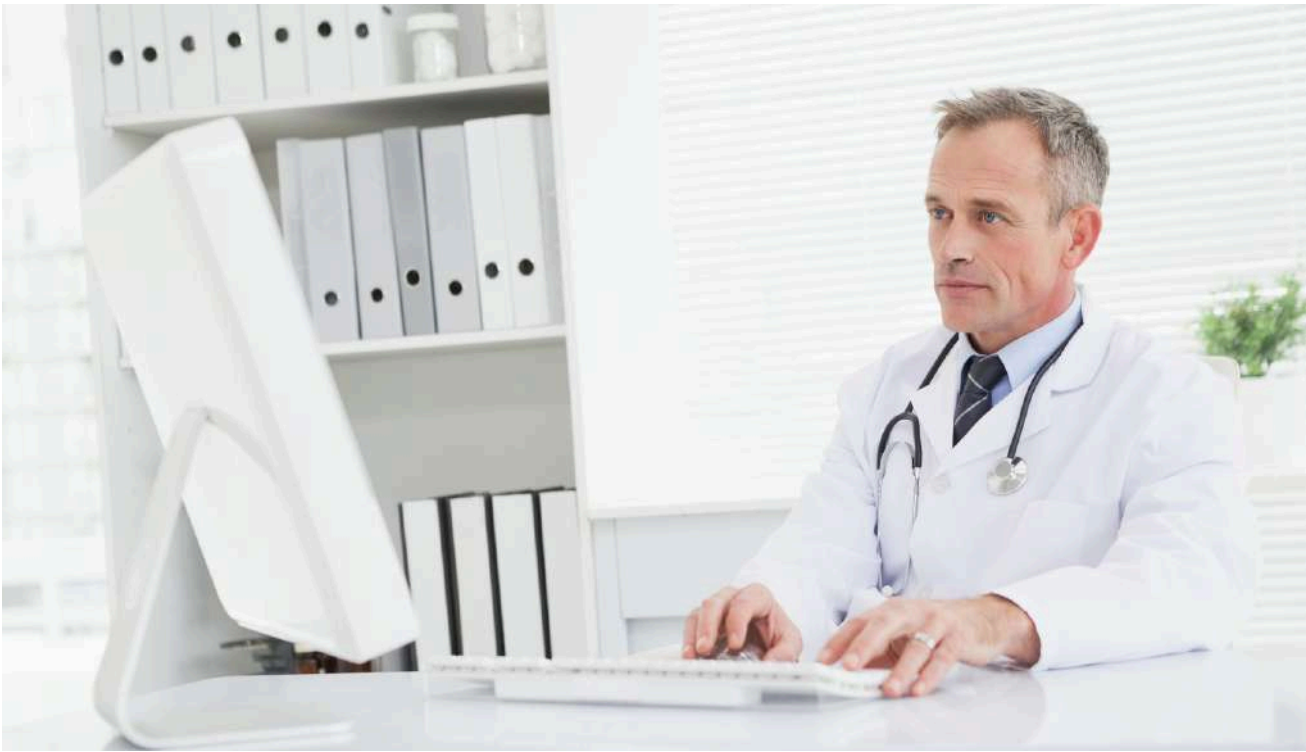
Manufacturers are responsible for monitoring the safety of their drugs through risk management plans, including pharmacovigilance programs aimed at collecting and evaluating adverse reaction reports and taking necessary measures to reduce risks to patients. Pharmaceutical companies holding Marketing Authorization are required to have a pharmacovigilance responsible person.



WHO IS AND WHAT DOES THE PHARMACOVIGILANCE RESPONSIBLE DO?

The pharmacovigilance responsible, also known as the Qualified Person for Pharmacovigilance (QPPV), is a key figure within a pharmaceutical company tasked with managing and coordinating pharmacovigilance activities. Among their main tasks is the continuous monitoring of reports of adverse reactions and other adverse events related to the use of drugs. Additionally, the pharmacovigilance responsible is responsible for managing the safety database dedicated to pharmacovigilance, communicating with relevant regulatory authorities, ensuring compliance with current regulations, and managing related documentation, such as the Pharmacovigilance System Master File.





WHAT IS A PHARMACOVIGILANCE SAFETY DATABASE?

A safety database represents an essential tool for pharmaceutical companies in monitoring and managing pharmacovigilance cases. These databases allow for the recording, collection, and sharing of reports related to adverse events associated with the use of drugs.

Pharmaceutical companies are legally required to collect all pharmacovigilance reports and conduct periodic analyses to promptly identify potential risks to drug safety.

Moreover, regulatory requirements mandate that pharmacovigilance reports be transmitted between companies and regulatory authorities in a standardized electronic format, currently ICH E2B (R3). This format enables, among other things, a data encryption system during transmission to ensure the security of sensitive information.

Thanks to safety databases like SafetyDrugs, pharmaceutical companies can centralize all information related to pharmacovigilance cases, facilitating management, analysis, and data sharing in compliance with current regulatory provisions.

WHAT IS THE PHARMACOVIGILANCE SYSTEM MASTER FILE?

The Pharmacovigilance System Master File (PSMF) is a mandatory document required by European legislation on pharmacovigilance for all marketing authorization holders of medicinal products for human use in the European Union. The PSMF contains a detailed description of the company's pharmacovigilance system, including procedures, responsibilities, and resources employed for drug safety monitoring.

WHAT IS THE ACTIVE PHARMACOVIGILANCE?

Active pharmacovigilance is a proactive approach to drug safety surveillance, contrasting with passive pharmacovigilance. In active pharmacovigilance, active methods are used to identify and collect information on adverse drug effects, rather than waiting for spontaneous reports from physicians, patients, or healthcare providers.

Active pharmacovigilance activities may include post-marketing clinical studies, monitoring of health databases, epidemiological investigations, and other systematic research methods to identify potential signals of adverse drug reactions. This approach allows for the more timely and comprehensive identification of drug adverse effects, thereby contributing to improving the safety and quality of pharmacological therapy.

WHAT IS THE PASSIVE PHARMACOVIGILANCE?

Passive pharmacovigilance relies primarily on voluntary reports of adverse events from drug users. These reports are sent to regulatory agencies and pharmacovigilance centers, where they are recorded, analyzed, and evaluated to determine any correlations between the drug and the reported adverse event.

Passive pharmacovigilance has some limitations, such as underreporting of cases, lack of detailed data, and inability to establish the cause of reported adverse events with certainty. However, despite these limitations, passive pharmacovigilance remains a fundamental tool in monitoring drug safety after their marketing and in protecting patients' health.



WHAT IS THE DIFFERENCE BETWEEN PHARMACOVIGILANCE AND PHARMACOSURVEILLANCE?

The main difference between pharmacovigilance and drug surveillance lies in the approach and objective.

Pharmacovigilance is a system that deals with the collection, analysis, and interpretation of data regarding adverse drug effects after their marketing.

Pharmacosurveillance is a broader concept: it refers to the comprehensive monitoring of drug safety, efficacy, and appropriate use throughout their life cycle, including development, approval, marketing, and clinical use phases. Therefore, pharmacovigilance is a specific component of pharmacosurveillance.

HOW TO REPORT AN ADVERSE EVENT?

In Italy, patients can report an adverse reaction to their doctor or healthcare provider, or they can directly fill out the reporting form available on the AIFA (Italian Medicines Agency) website and submit it to the competent authority or the involved pharmaceutical company.

Pharmaceutical companies, on the other hand, generally receive reports electronically from authorities through safety databases. However, they may also be the first to receive a report through specific channels made available to the public and subsequently submit it to the competent authority.



WHAT ARE SERIOUS REACTIONS?

A reaction is defined as serious when:

- It is fatal;
- It has caused or prolonged hospitalization;
- It has caused severe or permanent disability;
- It has endangered the patient's life
- It has caused congenital abnormalities and/or birth defects;
- It reports a clinically relevant event regardless of consequences (IME Important Medical Event list);
- Lack of efficacy is reported for some products such as life-saving drugs, contraceptives, vaccines;
- It is any suspected transmission of an infectious agent through the drug;
- It is any reaction attributable to:
 - congenital, familial, and genetic disorders;
 - benign, malignant, and unspecified neoplasms (including cysts and polyps);
 - infections and infestations.



WHAT IS THE IME LIST?

The IME list, acronym for Important Medical Event, is a list published by the European Medicines Agency (EMA) containing specific terms used to classify suspected adverse drug reactions in terms of severity. This list is used as a tool to facilitate the classification of adverse reactions and to support the assessment of drug safety.

The terms listed in the IME list are considered important because they indicate events that can have a significant impact on the patient's health or require particular attention during clinical use of drugs. The IME list is used by healthcare professionals and pharmacovigilance experts to quickly identify and classify suspected adverse reactions based on their severity and to support the analysis of drug safety data.

It is important to emphasize that the IME list is dynamic and subject to periodic revisions to ensure its accuracy and relevance in assessing drug safety. Healthcare professionals and pharmacovigilance experts should refer to the most recent version of the IME list provided by the EMA to ensure a correct and updated assessment of adverse drug reactions.

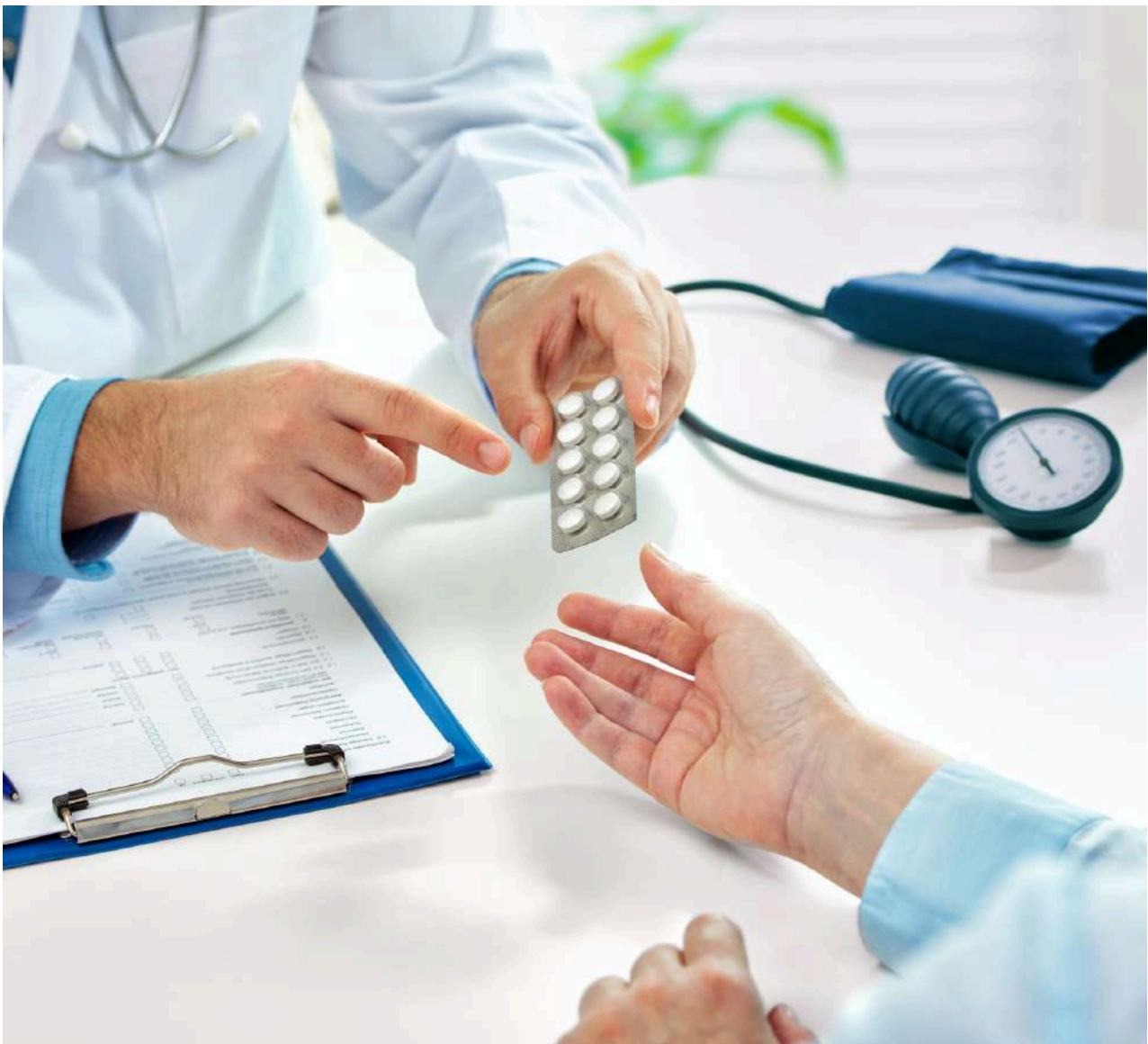
WHAT DOES OFF-LABEL USE OF A DRUG MEAN?

Off-label use of a drug occurs when a medicinal product is prescribed, administered, or used in a manner different from that approved by competent regulatory authorities. In other words, off-label use occurs when a physician uses a drug for an indication, dose, route of administration, or category of patients different from those specifically approved.

Off-label use generally occurs in cases

where there is a lack of approved alternatives to treat a specific medical condition, therefore, it is lawful, but it is important that the physician has a valid clinical basis for prescribing the drug off-label and that the treatment is supported by scientific evidence.

Since off-label use involves the absence of specific data on efficacy and safety for the unapproved indication, it may entail additional risks for patients, who must be carefully monitored for any adverse outcomes.



PHARMACOVIGILANCE IN 2024: HOW THE EUROPEAN LANDSCAPE IS CHANGING

EUROPEAN PHARMACOVIGILANCE HAS GONE THROUGH A PERIOD OF PROFOUND CHANGE OVER THE PAST YEAR, DRIVEN BY NEW REGULATIONS AND INNOVATIVE TECHNOLOGIES. HERE ARE THE MAINLY NEWS.

GVP XVI REVISION

The revision of GVP XVI came into force in August 2024, introducing updated guidelines for risk minimization. One of the main innovations introduced was Addendum II, which provides detailed guidance on how to assess the effectiveness of risk minimization measures through structured data sources and advanced search methods.

EUDRAVIGILANCE

Over the past few months, EudraVigilance, the European system for collecting and analyzing reports of suspected adverse reactions, has undergone significant improvements to optimize its efficiency and reliability. Among the main innovations are new business rules that make the management of Individual Case Safety Reports (ICSR) clearer and more structured, reducing errors in data transmission. In addition, technical updates have been implemented to improve the stability of the system, reduce disconnections and speed up response times, thus offering users a smoother and more reliable experience.

EMA ACCOUNT

The management of access to the EMA system has also been revised. New multi-factor authentication options and more specific user roles have been introduced. These updates, which also include the possibility to upload documentation directly when requesting a role, reflect a commitment to security and operational convenience.



XEVMPD

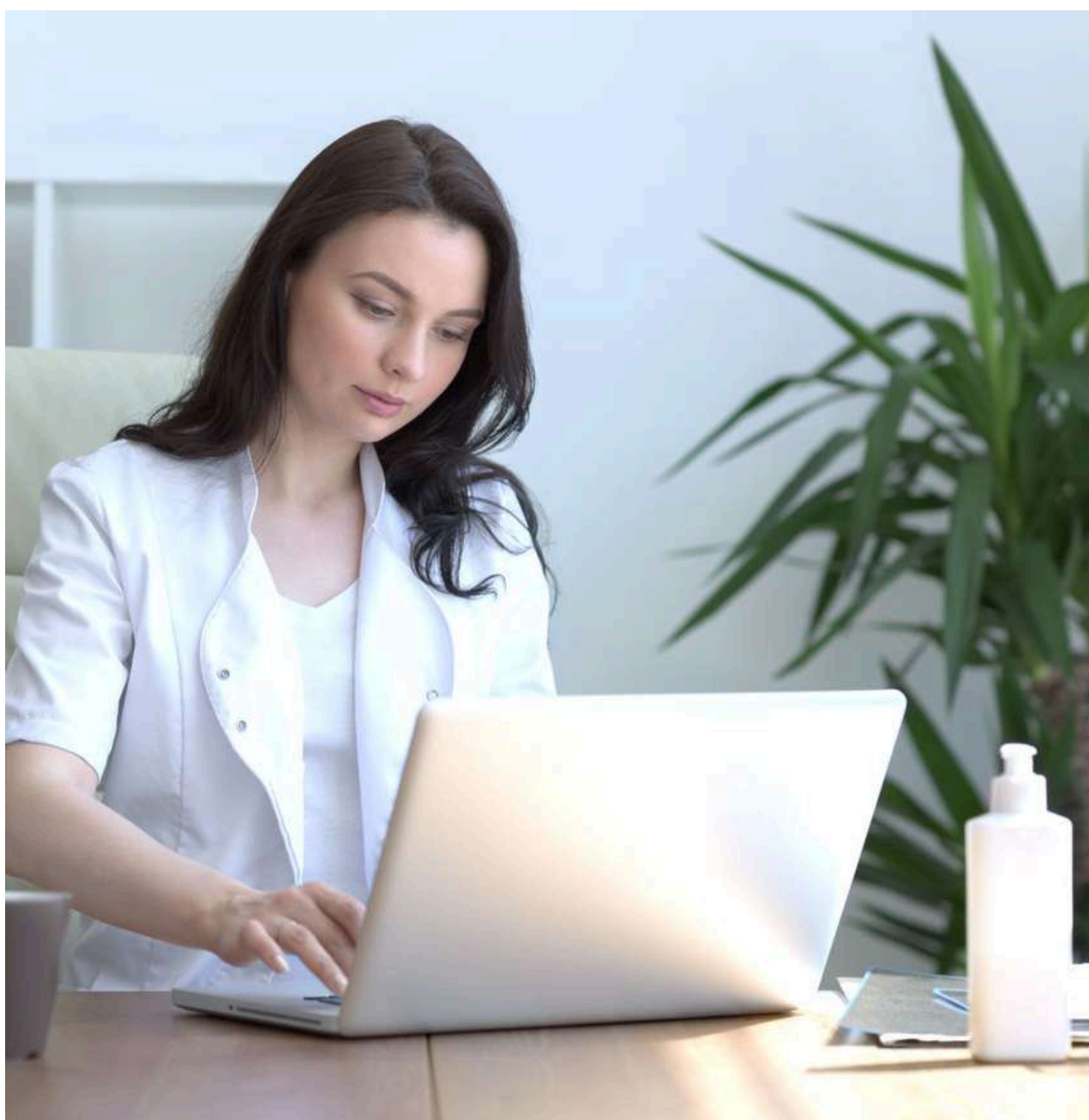
The update of the XEVMPD system marks the start of the transition to the new Product Management Service (PMS). The EMA has provided detailed guidance on how to verify and improve data quality, with a particular focus on pack sizes. This step requires a high level of precision to ensure a smooth migration.

PRODUCT MANAGEMENT SERVICE

The Product Management Service, which will replace XEVMPD, is an advanced platform for managing data on authorised medicinal products. In addition to improving data transparency and integrity, the system supports key applications such as ePI, Regulatory Procedure Management and the European Shortages Monitoring Platform (ESMP), demonstrating its central role in future regulation.

ARTIFICIAL INTELLIGENCE

The integration of Artificial Intelligence (AI) in pharmacovigilance has been one of the most debated topics in recent months. With the publication of the “Guiding Principles for the Use of Large Language Models”, the EMA has set a clear path for the ethical and safe use of these technologies. AI promises to revolutionise data analysis, improving the ability to detect safety signals and optimising management processes.



GVP XVI REVIEW: RISK MINIMIZATION UPDATES

THE REVISION OF MODULE XVI OF THE GOOD PHARMACOVIGILANCE PRACTICES (GVP) BY THE EUROPEAN MEDICINES AGENCY (EMA) REPRESENTS A SIGNIFICANT STEP FORWARD IN THE REGULATION OF PHARMACOVIGILANCE IN THE EUROPEAN UNION. PUBLISHED ON 26 JULY 2024 AND COMING INTO FORCE ON 6 AUGUST 2024, THIS THIRD REVISION INTRODUCES IMPORTANT UPDATES RELATING TO RISK MINIMISATION MEASURES (RMM) AND THEIR MANAGEMENT.

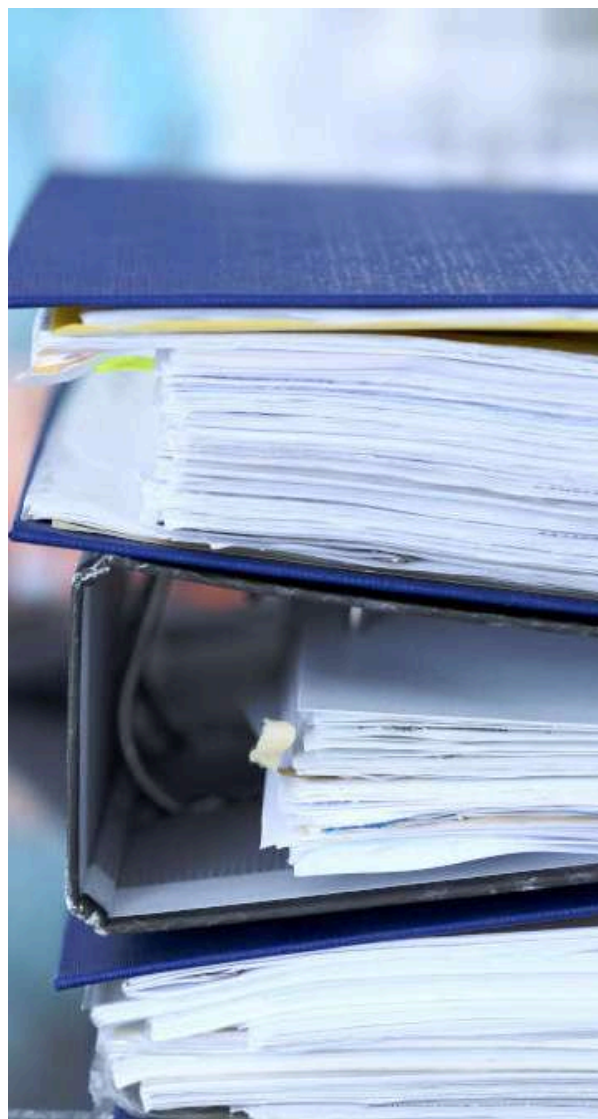
OBJECTIVES AND PRINCIPLES OF THE REVISION OF GVP XVI

The revision of GVP XVI focuses on the integration of RMMs into the benefit-risk management cycle of medicinal products, providing detailed guidance on how these measures can be implemented, monitored and evaluated. The main aim is to make RMMs more effective by promoting robust evidence-based risk management.

The new guidance applies to three main areas:

- New marketing authorisations.
- New risk minimisation measures.
- New studies to assess the effectiveness of RMMs in already authorised medicines.

However, these guidelines do not apply immediately to existing RMMs or ongoing activities. If changes to existing measures are needed, it will be essential to take the review into account, especially if these changes can improve the effectiveness of RMMs without compromising patient and healthcare professional familiarity with the medicine.





ADDENDUM II: : NEW STANDARDS FOR EVALUATING EFFECTIVENESS

A key element of the review is the introduction of Addendum II, which establishes new standards for assessing the effectiveness of RMMs. This document provides guidance on three key aspects:

- Data sources: the use of standardized databases and registries is suggested to ensure the quality and consistency of analyses.
- Research methodologies: structured approaches, such as observational studies and advanced statistical methods, are recommended to assess the measures adopted.
- Reporting: greater transparency and standardization in the presentation of the results of effectiveness studies is promoted.

IMPLICATIONS FOR PHARMACEUTICAL COMPANIES

Pharmaceutical companies are called upon to rapidly adapt to these new guidelines, integrating them into their risk management plans (RMPs). In particular, they must adopt a more structured approach to planning and continuous evaluation of RMMs, ensuring that the measures adopted are effective and evidence-based. This not only ensures compliance with regulatory requirements, but also strengthens patient safety and the effectiveness of managing risks associated with medicinal products.

AGGIORNAMENTI EUDRAVIGILANCE: MIGLIORIE PER UNA GESTIONE PIÙ EFFICIENTE



EUDRAVIGILANCE, THE EUROPEAN UNION'S CENTRAL SYSTEM FOR COLLECTING AND ANALYSING ADVERSE DRUG REACTION REPORTS, HAS UNDERGONE MAJOR UPDATES IN 2024. THESE CHANGES AIM TO IMPROVE THE QUALITY OF THE DATA MANAGED AND THE OPERATIONAL EFFICIENCY OF THE SYSTEM, MAKING IT AN EVEN MORE RELIABLE SUPPORT FOR PHARMACOVIGILANCE ACTIVITIES.

MAIN CHANGES TO EUDRAVIGILANCE

Among the most notable changes introduced, a new information notice on EVWEB stands out, which clarifies the implications of the nullification of an Individual Case Safety Report (ICSR). The system now specifies that:

1. Nullification always concerns the entire ICSR, not individual versions;
2. Once an ICSR is nullified, it is not possible to send subsequent follow-ups for that case;
3. In case of an error in the selection of the EV module, the report must not be nullified, but corrected and resubmitted to the correct module.

This measure was introduced to avoid common errors, providing clear instructions to users and improving data management.

Another innovation is the addition of a new business rule, which rejects amendment reports submitted without a previous version registered in the system. This rule was necessary to address a

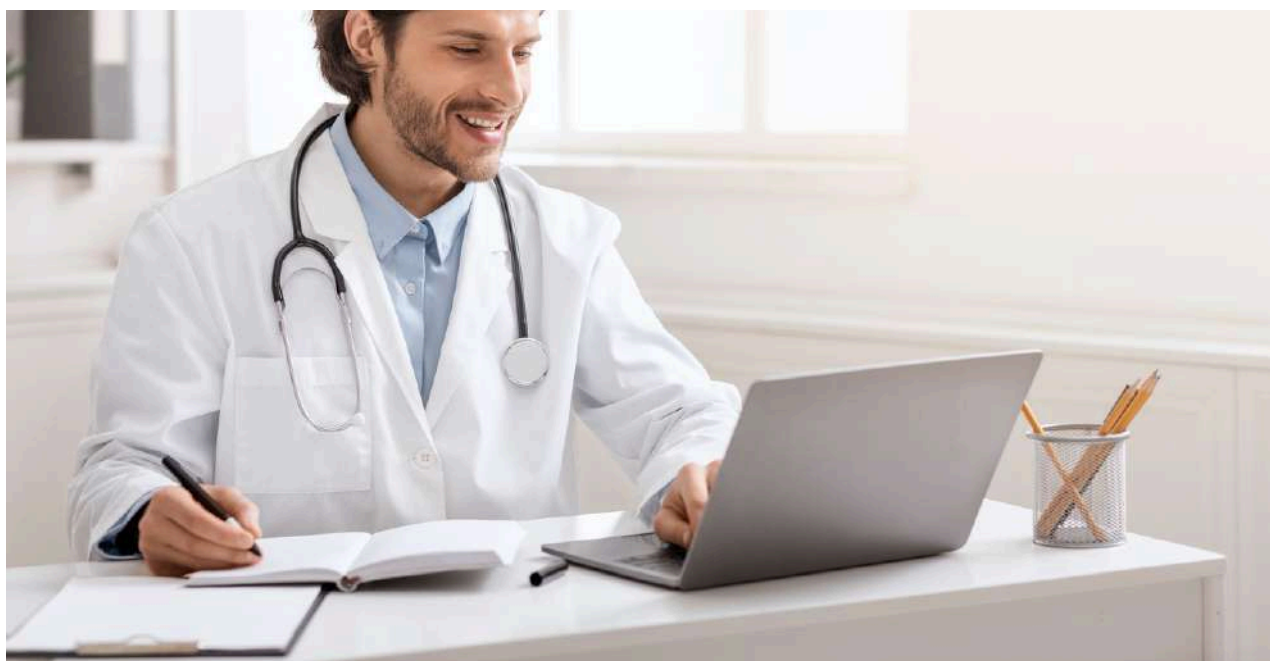
widespread problem: some companies mistakenly used amendment reports to resubmit cases rejected by EudraVigilance. This practice stemmed from a misinterpretation of the function of amendment reports, often confused with changes to a case without new data or changes to the starting date of Day 0. Now, rejected reports must be corrected and resubmitted, rather than treated as amendments.

PERFORMANCE IMPROVEMENTS

In addition to the new features, EudraVigilance has seen an overall improvement in its performance, including:

- Significant reduction in disconnections during use;
- Faster times for receiving acknowledgments;
- Increased availability of the system, which can now also be used outside EMA working hours.

These improvements reflect EMA's commitment to making EudraVigilance an increasingly stable and reliable tool for pharmacovigilance professionals.

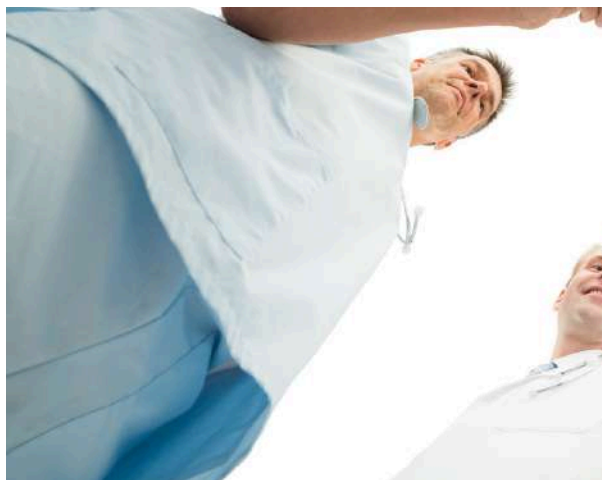


EMA ACCOUNT MANAGEMENT: NEW FEATURES AND UPDATES FOR EASIER AND MORE SECURE MANAGEMENT

DURING 2024, EMA ACCOUNT MANAGEMENT, THE PLATFORM USED TO MANAGE ACCESS TO THE EUROPEAN MEDICINES AGENCY (EMA) SYSTEMS, HAS INTRODUCED NUMEROUS NEW FEATURES TO SIMPLIFY THE USER EXPERIENCE AND IMPROVE SECURITY.

THE PLATFORM: AN ESSENTIAL GATEWAY

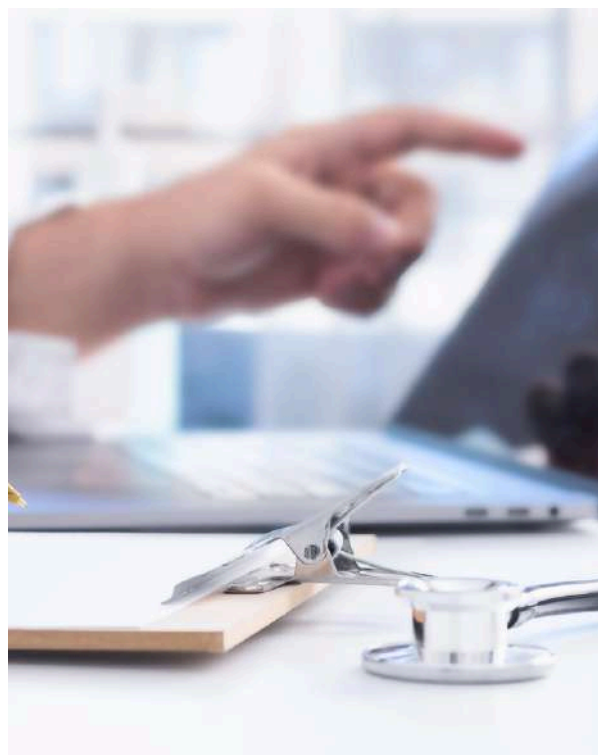
EMA Account Management is the access point for interacting with the agency's main applications, such as EudraVigilance, SPOR and CTIS. Through this platform, users can create an account, retrieve credentials, request specific access and manage permissions for their organizations. Furthermore, with the support of multifactor authentication, the security of digital interactions is guaranteed, without compromising ease of use.



EMA ACCOUNT: NEW FEATURES INTRODUCED IN 2024

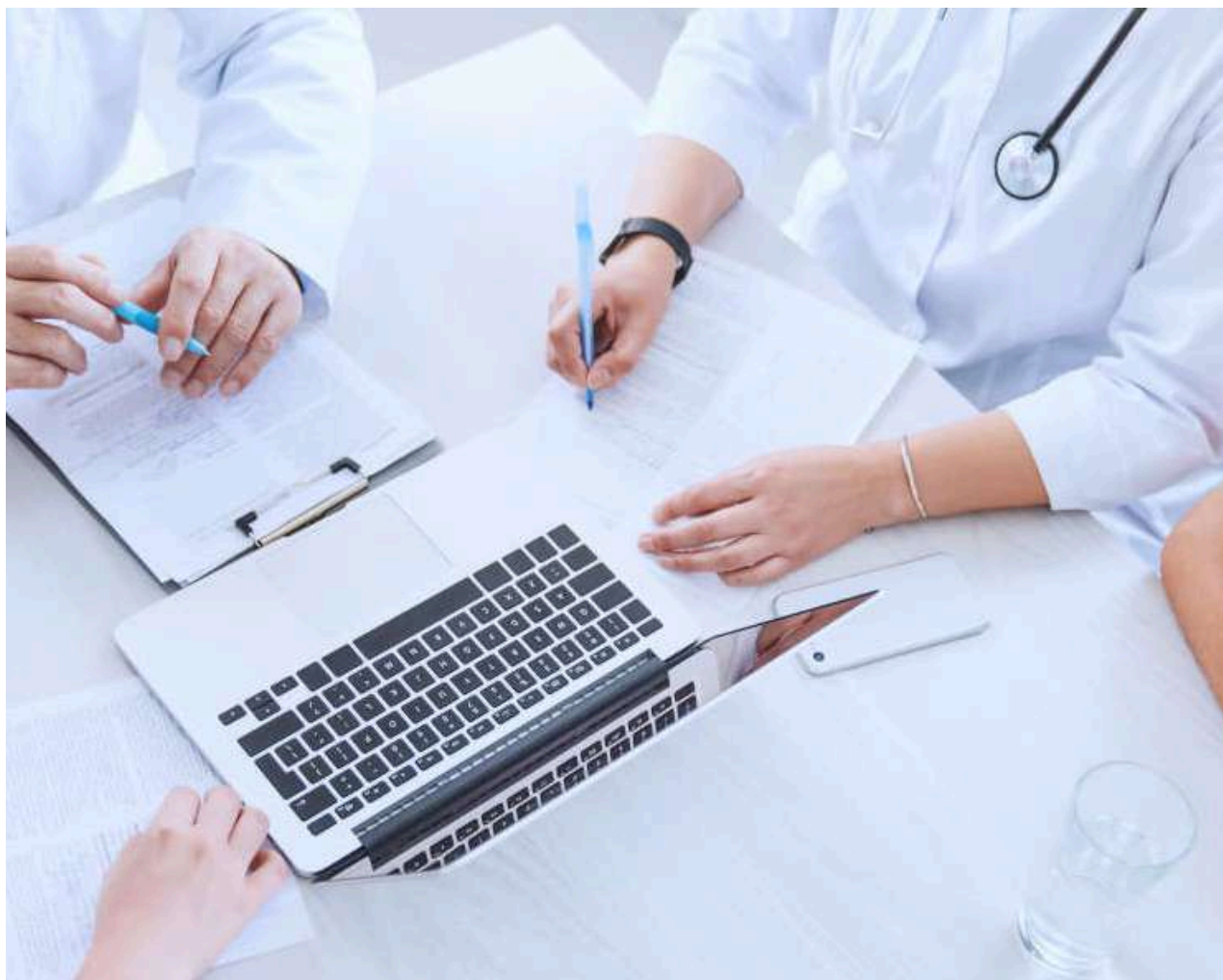
Among the most significant updates are:

1. Email authentication. From 30 September 2024, all new users can access EMA systems using email authentication, a simpler and more secure system. This mode replaces the username and password with a One-Time Passcode (OTP) sent to the user's email address. Existing users have the option to activate this feature through an opt-in process available in the platform menu. To facilitate the transition, EMA is sending regular reminders, and from January 2025, email authentication will become mandatory for all accounts. This change improves usability and reduces issues related to credential retrieval.
2. Self-closing accounts. If you no longer need an EMA account, you can now self-close it via a dedicated option in the menu. Users who leave an organization or change roles can then terminate their account without having to contact the Service Desk. However, administrators must ensure that key responsibilities, such as the User Administrator role, are transferred before closure.
3. Advanced role management and connection with OMS. EMA has improved role management through an integration with the Organization Management Services (OMS) system, which allows users to search and select their organization before requesting a specific role. New roles have also been added for the Product Management System (PMS), part of the SPOR project, including the Product User Interface and the Industry Qualified User. For some requests that require supporting documentation, users can now upload



files directly during the request process, reducing the time and complexity of the approval process. To complement this approach, EMA has introduced predefined templates that simplify the compilation and submission of the necessary documentation, ensuring greater transparency and compliance with regulatory standards.

4. Advanced access management. EMA has introduced tools to simplify access management:
 - With the organizational shopping cart, users can add multiple organizations to a single request, speeding up the selection process.
 - Organizational mergers are now signaled with notifications to administrators, who can review and update access to ensure consistent management.
 - Finally, inactive locations are now clearly identified and not selectable, improving clarity and reducing errors.



A SMOOTHER TECHNICAL EXPERIENCE

In addition to the new features, EMA has worked to improve the technical efficiency of the platform. Users can benefit from:

- Automatic cleanup of disabled accounts, which eliminates access for those who leave an organization.
- Validation of contact data at each login, ensuring information is always up to date.
- Simplified integration with collaborative tools such as Microsoft Teams and SharePoint, without having to change accounts or use complex methods.

AN INCREASINGLY MODERN FUTURE

With these innovations, EMA confirms its commitment to improving the security and ease of use of the platform. Email authentication, advanced access management and technical optimizations represent a step forward towards a smoother and more effective user experience. For those who interact with EMA systems, these innovations not only simplify processes, but also guarantee a higher level of security, adapting to the needs of an increasingly digital landscape.

ARTIFICIAL INTELLIGENCE AND EMA: INITIATIVES FOR USE IN PHARMACOVIGILANCE

DURING 2024, EMA PUBLISHED TOOLS AND GUIDELINES TO INTEGRATE ARTIFICIAL INTELLIGENCE INTO PHARMACOVIGILANCE PROCESSES. HERE THEY ARE.



The European Medicines Agency (EMA) is taking significant steps towards integrating Artificial Intelligence (AI) into its regulatory and scientific activities. It has introduced a [section dedicated to AI on its official website](#) and published a document entitled “Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities”, a document that provides guidelines on the use of large language models (LLM).

THE SECTION ON THE EMA WEBSITE DEDICATED TO AI

EMA has created a section dedicated to AI on its official website, a point of reference for those working in the pharmaceutical and regulatory sector. This page, part of the Big Data program, provides an overview of the initiatives to integrate AI into European regulatory processes, with a focus on innovation, safety and transparency. Here is an overview of the main topics covered in the section.

The AI work plan: a framework for the future

The page presents the AI work plan for the period 2023-2028, developed by the Big Data Steering Group, which identifies four key areas of intervention:

- product guidance and support. Providing guidance on the use of AI throughout the lifecycle of medicines;
- AI tools and technologies. Developing frameworks for the implementation of AI-based tools, ensuring safety and reliability;
- collaboration and training. Strengthening the skills of operators through learning programmes;
- experimentation. Promoting the adoption of a structured approach to testing and integrating AI technologies.

These initiatives not only foster innovation, but also aim to ensure that the adoption of AI occurs in a responsible manner, with particular attention to risks and safety.

Reflections on AI and the lifecycle of medicines

Another important element of the EMA section on AI is the reflection paper "*The use of artificial intelligence (AI) in the lifecycle of medicines*", which provides guidance for developers and pharmaceutical companies to use AI and machine learning safely and effectively during the different phases of a medicine's lifecycle.

The main objective is to ensure that AI technologies can be used to improve quality, reduce time and optimise processes, without compromising patient safety or regulatory compliance.



Practical initiatives: the case of the Scientific Explorer

In March 2024, the EMA introduced the Scientific Explorer, an AI-based tool designed to make it easier for authorities to find scientific regulatory information. This tool is a concrete example of how the agency is using AI to improve data efficiency and accessibility.

Public consultation

The EMA page highlights a public consultation regarding an AI model used in the determination of disease activity in liver biopsies. This initiative demonstrates the EMA's commitment to engaging industry experts and stakeholders to ensure transparency and collaboration in the adoption of AI technologies.



The use of Large Language Models

The “Guiding Principles for the Use of Large Language Models” document is also available, a guide that establishes guidelines for the use of advanced language models in medicines regulatory activities.

Large Language Models (LLMs) are generative AI models, trained on large sets of textual data, that can generate natural language responses to specific inputs. In the regulatory context, LLMs find application in tasks such as automatic document processing and data analysis.

Guiding Principles for the safe and effective use

The EMA document outlines several principles for the safe and effective use of LLMs:

- data security. Ensure that data input into models is done in a secure manner, protecting the confidentiality and integrity of information;
- critical thinking. Apply a critical approach in evaluating the outputs generated by models, verifying their accuracy and relevance;
- continuous learning. Promote a constant updating of skills and knowledge related to the use of LLMs, to adapt to technological evolutions;
- governance: establish clear governance to guide the responsible use of LLMs within regulatory authorities.

These principles aim to ensure that AI is used in an ethical, transparent and safe manner, while minimising the risks associated with its use.

CHALLENGES AND OPPORTUNITIES

EMA recognises that, although LLMs offer significant opportunities to improve the efficiency and effectiveness of regulatory activities, there are also challenges, such as the risk of “hallucinations”, i.e. the generation of plausible but inaccurate information. Therefore, it is crucial to implement control and validation measures to mitigate these risks.

COLLABORATION AND TRAINING

The document highlights the importance of collaboration between different regulatory authorities and the need for continuous training for staff, in order to ensure the effective and responsible use of LLMs in regulatory activities.

A BALANCE BETWEEN INNOVATION AND SAFETY

EMA is working to integrate AI into regulatory processes in a responsible way, balancing innovation and safety. With initiatives such as the new section on AI, the 2023-2028 work plan and the guiding principles on LLMs, the agency demonstrates its commitment to the conscious use of emerging technologies.

For pharmaceutical companies, these initiatives represent not only a regulatory challenge, but also an opportunity to improve data management and optimise processes. However, adopting AI requires a critical and well-planned approach, to maximize benefits while minimizing risks.



AFI SYMPOSIUM 2024: THE LATEST FROM THE PHARMACEUTICAL WORLD

THE 63RD EDITION OF THE AFI SYMPOSIUM HAS JUST CONCLUDED. HELD FROM JUNE 5 TO 7, 2024, AT THE PALACONGRESSI DI RIMINI, THE EVENT EXPLORED KEY TOPICS IN THE PHARMACEUTICAL FIELD. HERE'S A SESSION-BY-SESSION OVERVIEW OF WHAT WAS DISCUSSED.




AFI SYMPOSIUM 2024: THE EVENT

From 5 to 7 June 2024, the Palacongressi in Rimini hosted the 63rd edition of the AFI Symposium, an important moment of meeting and exchange between the protagonists of scientific research and companies in the sector.

The AFI Symposium is divided into numerous scientific sessions, workshops and exhibition areas, offering a unique opportunity for updating and networking for professionals in the sector.

Each edition of the Symposium is dedicated to specific themes of great relevance to the pharmaceutical industry: this year's is The Challenges of the Health Industry: Research, Innovation, Sustainability.

The topics discussed this year ranged from sustainability in the pharmaceutical industry to the complexity of the supply chain, from innovation in packaging materials to the growing importance of digital health. Here is the program.



AFI SYMPOSIUM 2024: THE PROGRAM

WEDNESDAY, JUNE 5

- Company Workshops
- Wednesday's Scientific Sessions
 - Marcello Cattani's Lectio Magistralis
 - Session I - Energy and Sustainability
 - Session II - Supply Chain
 - Session III - Packaging Materials
 - Session IV - Digital Health
- Startup Square

THURSDAY, JUNE 6

- Thursday's Scientific Sessions
 - Session V - Clinical Research
 - Session VI - Quality
 - Session VII - HTA
 - Session VIII - Deblistering
 - Session IX - Environmental Risk Assessment
 - Session X - Pharmaceutical Sciences
 - Session XI - Biotech
 - Session XII - Pharmacovigilance
 - Session XIII - Medical Devices
 - Session XIV - Advertising and IMS in the Health Area
 - Session XV - CRS-SITELF
- Women's Square
- Poster Session

FRIDAY, JUNE 7

- Friday's Scientific Sessions
 - Session XVI - Parenteral Drugs
 - Session XVII - Innovation
 - Session XVIII - APIs
 - Session XIX - Special Productions
- Workshops and Special Areas

SESSION I – ENERGY AND SUSTAINABILITY

The first session delved into various aspects related to energy and sustainability in the pharmaceutical sector. Discussions focused on integrating environmental, social, and economic responsibilities into the daily activities of pharmaceutical companies, highlighting the importance of fostering a corporate culture that embraces responsible and ethical business practices. Present and future regulatory requirements were analyzed, and practical experiences of ecological efficiency projects in departments and laboratories were shared. The session underscored the fundamental and interconnected nature of safety and sustainability in the daily operations of companies in the sector.

SESSION II - SUPPLY CHAIN

The Supply Chain session examined the growing complexities in the pharmaceutical sector that significantly impact supply chain management. As products, regulations, sales channels, and markets continuously evolve, the pharmaceutical supply chain faces new challenges in managing medicines post-production. Various aspects involving not only pharmaceutical companies but also downstream process operators, such as primary distribution through multi-mandate warehouses, intermediate distribution via wholesalers, transportation, and hospital and community pharmacies, were explored. These insights highlighted current challenges and the ongoing solutions to enhance efficiency and safety in the pharmaceutical supply chain.

SESSION III – PACKAGING MATERIALS

This session presented various aspects related to the production, control, and use of primary and secondary packaging materials for medicines. Following an introduction on the general aspects of controlling and using these materials in medicine production, the session featured several presentations on specific topics related to the production and control of packaging materials. Key discussions included coupled materials for blister production, elastomeric closures, secondary packaging materials, and glass containers, providing a comprehensive and detailed overview of the challenges and solutions in the use and control of packaging materials in the pharmaceutical sector.



SESSION IV - DIGITAL HEALTH

The digital health session explored the impact of new technologies in the healthcare sector. The primary focus was on the increasing use of AI-based technologies and the introduction of digital therapies. The session highlighted the benefits of a multidisciplinary approach to evaluate these technologies from legal, technological, practical, and sustainability perspectives. Case studies, patient impact, privacy implications, and associated business models were discussed. The session provided an overview of the current market status, exploring the risks and opportunities associated with adopting these innovative technologies in the healthcare sector.



SESSION V - CLINICAL RESEARCH

The clinical research session discussed the benefits of introducing innovative and decentralized solutions in clinical trials. The effective use of wearable devices for data collection and remote monitoring was recognized for simplifying processes, reducing the burden on patients and clinical centers, and lowering costs. However, the significant impact of these transformations on sustainability was also emphasized. Presentations illustrated concrete examples of sustainability in clinical trials, highlighting recent methodological and regulatory changes. The discussions aimed to improve clinical studies, raising awareness among pharmaceutical companies, CROs, and regulatory bodies about the importance of designing and approving studies that benefit patients, hospitals, the healthcare system, and the environment.

SESSION IV - QUALITY

The quality-focused session addressed the implementation of quality systems in sectors other than pharmaceutical manufacturing plants. Various critical aspects of quality systems were discussed, including the importation of active pharmaceutical ingredients (APIs) and medicines, the distribution and transport of APIs and medicines, the production and distribution of medicinal gases, product development, clinical trial batch production, and the production of advanced therapies (ATMPs). A notable presentation by AIFA (Italian Medicines Agency) covered inspection and authorization aspects of these companies, highlighting the challenges and best practices in ensuring regulatory compliance and quality in the evolving pharmaceutical landscape.

SESSION VII - HTA

The HTA regulation, soon to be implemented, had its dedicated session. The primary objective of this regulation is to improve access to effective health technologies, ensuring uniform benefits for patients across all Member States. Nearly two years after its approval, the HTA will soon be applied in various States, including Italy. The session discussed the current state of HTA at both European and national levels, focusing on the Coordination Group and AIFA. The session explored the upcoming implementation phases, highlighting the significant initial impact the regulation will have on oncology drugs and advanced therapies (ATMPs). A central moment was the round table discussion, which took place exactly six months before the regulation's entry into force, allowing a wide range of stakeholders to coordinate for the initiative's success and the improvement of public health at both European and Italian levels.

SESSION VIII - DEBLISTERING

The deblistering session addressed the highly relevant issue of unit dose preparation in pharmacies. This field presents significant risks and opportunities. Participants received a comprehensive overview of the topic, including a round table discussion that analyzed experiences and practices adopted in Italy and Switzerland.

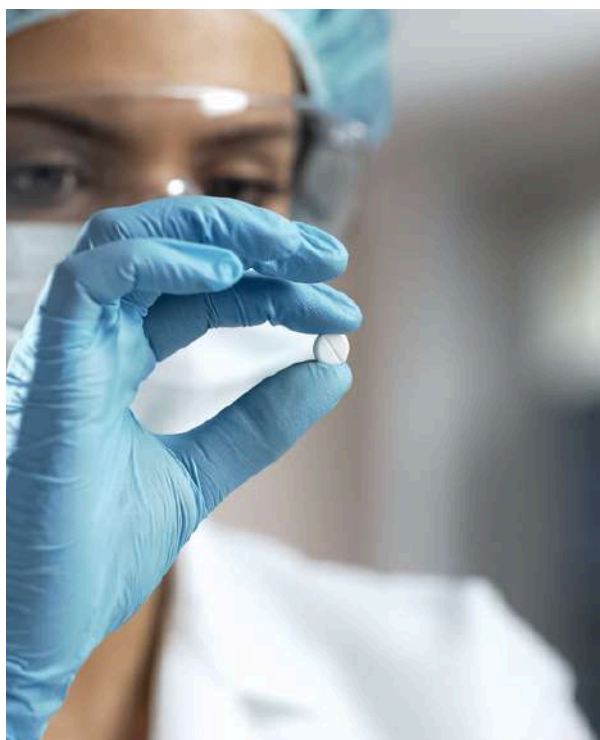
SESSION IX - ENVIRONMENTAL RISK ASSESMENT

The main objective of the session was to provide an overview of the current scientific and regulatory approach and the significant changes anticipated by the new European directive on pharmaceuticals. The session began with a brief exposition on the historical scientific approach recommended since the first EMA guidelines in 2006. Practical and applicative insights in the current context were then offered. Finally, different approaches from European authorities were explored, highlighting variations in perspectives and methodologies.



SESSIONE X - AFI - SITELF PHARMACEUTICAL SCIENCES

This session focused on the research and development of new therapeutic approaches for the treatment of endocrine diseases, with particular attention to diabetes therapy. Despite efforts in awareness and prevention, the number of people affected by diabetes continues to grow, especially type 2 diabetes, which accounts for over 90% of all diabetes cases and is often associated with other chronic diseases such as obesity, hypertension, and dyslipidemia. Clinical-pharmacological and social aspects related to diabetes were addressed, highlighting the importance of technological platforms, portals, chronotherapy, and new therapeutic approaches in treating this condition. Particular emphasis was placed on innovative drug delivery technologies and personalized pharmacological therapy for glycemic control.



SESSION XI - BIOTECH

The session explored the radical innovation represented by CAR-T, transforming treatment prospects for oncohematological diseases, solid tumors, and autoimmune diseases, conditions that until a few years ago had no effective solutions. CAR-T is revolutionizing medicine. The session featured leading experts in the field in Italy, discussing recent progress, technical and regulatory challenges, and future prospects for CAR-T in clinical practice. It was a crucial moment to understand how these technologies are radically changing the landscape of treating serious and incurable diseases.

SESSION XII - PHARMACOVIGILANCE

The pharmacovigilance session focused on the close correlation between quality complaints and their impact on patient health. It is widely recognized that problems or defects in drug quality can compromise patient health and therapy adherence. This topic was addressed through two technical presentations and a round table, aiming to discuss the processes involved and identify potential barriers. The importance of collaboration between Pharmacovigilance and Quality departments in managing the information necessary to fulfill legislative obligations was emphasized. AIFA's presentation focused on good pharmacovigilance practices (GVP) and the necessary corrective actions to ensure the safety and efficacy of medicines. L'intervento di AIFA si è focalizzato sulle buone pratiche di farmacovigilanza (GVP) e sulle necessarie azioni correttive per garantire la sicurezza e l'efficacia dei medicinali.

SESSION XIII - MEDICAL DEVICES

This session focused on the impact of the European Medical Device Regulation. The MDR introduced stricter harmonization criteria and restrictions for certifying new products, especially substance-based devices. Seven years after its publication, the benefits and disadvantages of the new regulation have emerged, with increased certification costs and longer, more uncertain times. This risk could limit innovation and reduce therapeutic options available to patients. The symposium highlighted the critical issues analyzed by the AFI Study Group and facilitated a discussion among various sector stakeholders to explore possible solutions.

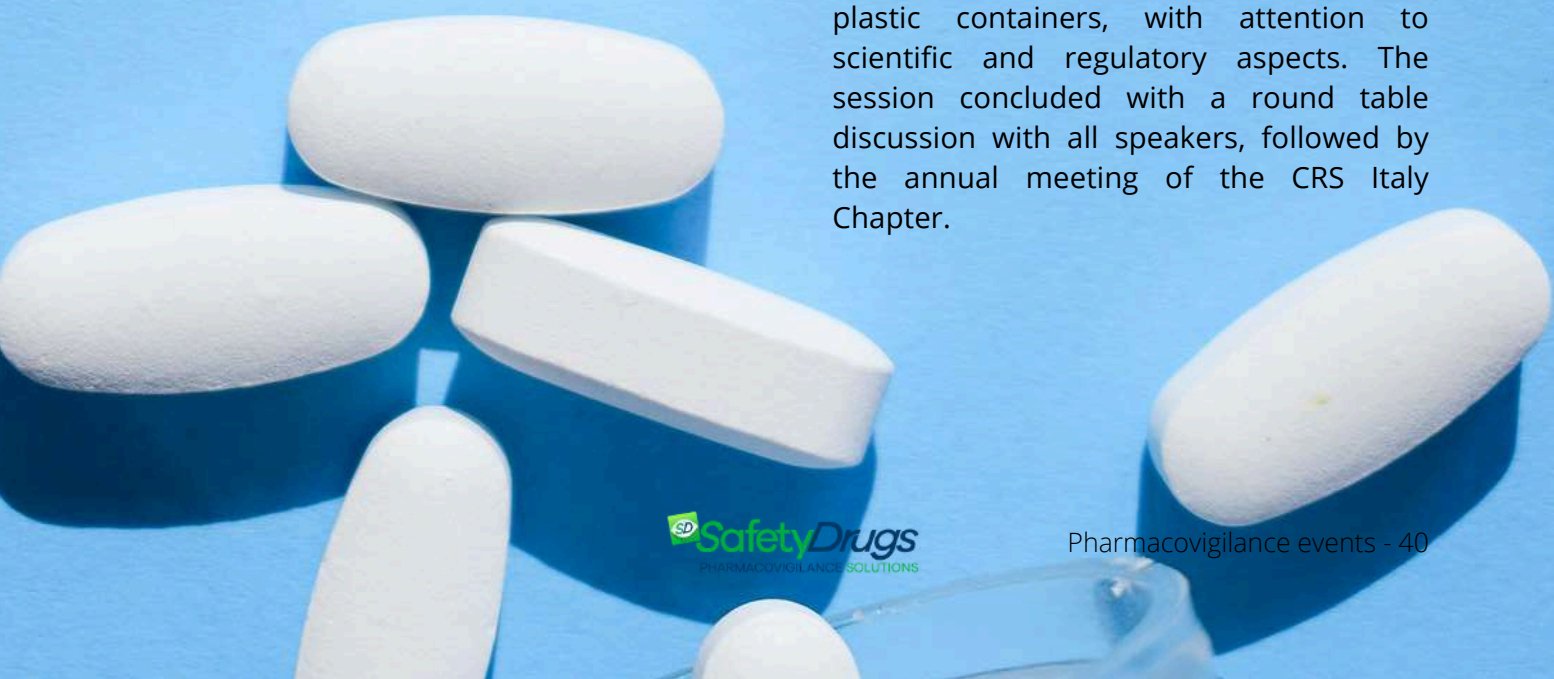
SESSIONE XIV - ADVERTISING AND IMS IN HEALTHCARE

The session focused on the rules and opportunities related to advertising and medical-scientific information in the digital context. Pharmaceutical companies must comply strictly with the provisions of Title VIII of Legislative Decree 219/2006 when promoting their medicines to the public or healthcare professionals. However, the practical application of these regulations has highlighted various issues, both related to interpreting the rules and the wide range of digital tools available today.

Additionally, the diversification of company products, ranging from medicines to medical devices, homeopathic medicines, and food supplements, introduces further regulatory complexities. The session aimed to present practical experiences from numerous companies in scientific information and advertising, illustrating the evolution of tools and promotion methods. This provided insights for a round table discussion with leading industry associations and the competent health authority to explore solutions and improvements in the application of regulations and the use of digital means for promoting health products.

SESSIONE XV - CRS - SITELF

The session explored the critical interactions between modified-release drug delivery systems and primary packaging materials, with a particular focus on new characterization techniques. Various key topics were discussed, including the surface properties of primary glass containers and the effect of steam sterilization on them. The integrity of the closure of pre-filled glass syringes for ultra-low temperature storage was evaluated. Additionally, the stability of mRNA carried in lipid nanoparticles in pre-filled syringes, crucial for effective mass vaccination against COVID-19, was examined. Another relevant topic was the analysis of leachables and extractables from primary plastic containers, with attention to scientific and regulatory aspects. The session concluded with a round table discussion with all speakers, followed by the annual meeting of the CRS Italy Chapter.



SESSION XVI - PARENTERALS

The session highlighted how the parenteral medicinal product sector is undergoing a significant transformation. On the one hand, the use of non-viral nanovectors for the delivery of genetic material is introducing new perspectives in therapeutic research, but also new challenges in drug development and manufacturing. On the other hand, the rigorous implementation of the Annex 1 guidelines starting from August 2024, which now also includes freeze-drying, imposes new requirements to ensure the quality, safety and efficacy of the final product. The session focused on the challenges related to these evolutions and explored possible solutions. Innovative formulation approaches were presented to

address clinical needs, with the aim of personalising therapy for each patient. Regarding freeze-drying, critical processes influencing product quality were reviewed and solutions to ensure compliance with Annex 1 were discussed, including the introduction of innovative technologies in continuous manufacturing. A focus was also dedicated to the methods for verifying the integrity of rigid and flexible containers, underlining the importance of quality in the life cycle of the pharmaceutical product. Finally, a discussion was planned with a representative of the AIFA inspection area regarding the application of Annex 1 in the national context, followed by an interactive debate with the possibility of questions to the speakers.



SESSION XVII - INNOVATION

The session aimed to explore crucial topics in current and future technological innovation. The main objective was to analyze the opportunities and risks arising from the use of technology, focusing on three specific areas: artificial intelligence, digitalization of processes and validation and qualification 4.0 GAMP5 2.0.

First, artificial intelligence was discussed, trying to define it comprehensively and to examine the potential risks related to its improper use. AI was at the center of current technological discussions, often seen as a universal solution to multiple problems, although it was essential to understand the role of humans behind each of its applications. Concrete examples were presented of how AI could improve business processes, highlighting specific techniques and technologies used.

The second theme concerned the

digitalization of processes. The emphasis was placed on the importance of not making this transformation depend only on available technologies ("technology driven"), but rather of promoting an integrated strategy that involved the entire company organization. This inter-functional approach is crucial to achieving company objectives in terms of quality, efficiency and cost management of the services offered to customers. The last theme was the validation and qualification 4.0 GAMP5 2.0 for which the case of an SME that had undertaken a path aimed at achieving shared objectives in terms of quality, speed and costs of services was presented. This concrete example illustrated how the integration of people, processes and systems, supported by new technologies, could improve the integrity of company data and optimize the overall operations of the company.





SESSION XVIII - API

The session focused on recent European regulatory developments and their impact on the management of API manufacturers, with a special focus on registration procedures and necessary changes. A key theme was the growing focus on sustainability, with the presentation of the latest technological approaches both in development and industry, aimed at reducing the environmental impact of production processes and exploring their implementation prospects. Furthermore, in response to ongoing European

regulatory developments, an updated overview was provided on the situation of critical APIs, which are under attention due to the risk of shortages, and on the actions undertaken by authorities, such as the establishment of the Critical Medicines Alliance. This initiative involves all actors in the production chain and aims to prepare and manage health emergencies in Europe. The session also included a speech by representatives of AIFA, offering an opportunity to discuss regulatory and strategic issues of relevance for Italian API manufacturers.

SESSIONE XIX – SPECIAL PRODUCTIONS

The session focused on innovation in the specialty manufacturing sector, with a focus on Radiopharmaceuticals, Phytotherapeutics and Medicinal Gases.

The session started with two presentations that explored recent developments in Radiopharmaceuticals, highlighting the shift from predominantly diagnostic nuclear medicine to the increasing use of therapeutic drugs vectored with beta or alpha isotopes. These advances allow for better patient selection and more effective monitoring of therapy effects, integrating the concept of theragnostics. Another focus point was the use of artificial intelligence in the analysis of diagnostic images obtained with PET and SPECT radiopharmaceuticals, improving the processing of results and the personalization of therapeutic treatments.

Subsequently, two sessions were presented on technology based on plant cell suspension cultures. This approach represents a response to the search for sustainable sources of plant ingredients with a low environmental impact.

Suspension cultures allow for a more controlled and standardized production of phytotherapeutic extracts, eliminating environmental contamination and ensuring high safety and standardization.

Finally, for Medical Gases, the importance of sustainability and technological innovation in modern medicine was discussed, with concrete examples such as the use of Nitric Oxide for the treatment of pulmonary hypertension in Covid patients. These developments highlight the continuous opportunities for innovation in the medical gas sector, not only to improve treatments but also to promote more sustainable production practices.

AFI SYMPOSIUM: CONCLUSIONS

This year too, the AFI Symposium represented an opportunity for discussion between industry experts, companies and regulatory institutions, outlining future trends and strategies to address the challenges of the contemporary pharmaceutical landscape.



EU PHV CONGRESS 2024: AN EVENT ON PHARMACOVIGILANCE NOT TO BE MISSED



THE EUROPEAN PHARMACOVIGILANCE CONGRESS IS THE MUST-ATTEND EVENT FOR DISCOVERING THE LATEST ON PHARMACOVIGILANCE. HERE'S A LOOK AT THIS YEAR'S THEMES.

WHAT IS THE EUROPEAN PHARMACOVIGILANCE CONGRESS?

Now in its sixth edition, the [European Pharmacovigilance Congress](#) has become a key event in the field of pharmacovigilance. Featuring leading experts and international specialists, the event offers in-depth, up-to-date content focusing on the latest trends and emerging challenges in the sector.



THE AGENDA

The European Pharmacovigilance Congress 2024 will be held over 3 days in hybrid mode. The program is as follows.

Day 1

The following online sessions were held on November 18th, from 9am to 6pm.

09:00 AM – 09:15 AM Welcome and opening of the conference

09:15 AM – 10:50 AM Biological Basis of Adverse Reactions (with a focus on SCARs)

10:50 AM – 11:10 AM Coffee break & networking

11:10 AM – 12:30 AM Immunological Adverse Reactions or, in parallel, Communicating Safety Information in the Digital Era

12:30 AM – 1:45 PM Lunch & networking

1:45 PM – 3:20 PM Signal Detection

3:20 PM – 3:40 PM Coffee break

3:40 PM – 5:15 PM Risk Management or, in parallel, Risk Minimisation Measures

5:15 PM – 6:00 PM Lectio Magistralis

Day 2

On November 19th, from 9am to 6pm, were held.

09:00 AM – 09:10 AM Welcome and opening of the conference

09:10 AM – 10:45 AM Authorities' Assessment of PV Reports

10:45 AM – 11:05 AM Coffee break & networking

11:05 AM – 12:30 AM Real-World Data & Real-World Evidence or, in parallel, Evolving Landscape of Electronic Safety Data in PV

12:30 AM – 1:45 PM Lunch & networking

1:45 PM – 3:20 PM Manufacturing & PV Interfaces or, in parallel, Safety in Clinical Trials

3:20 PM – 3:40 PM Coffee break & networking

3:40 PM – 5:30 PM MedDRA or, in parallel, Non-EU PV Requirements

5:30 PM – 6:00 PM Lectio Magistralis

Day 3

On November 22, from 9:00 AM to 5:00 PM, sessions were held in person at the NH Milano Congress Center.

09:20 – 09:30 Welcome and opening of the conference

09:30 – 10:40 Evolving pharmacovigilance strategies

10:40 – 11:10 Coffee break & networking

11:10 – 12:50 Main global and local PV updates or, in parallel, Interactive workshop The Latest revisions of GVP guidelines on Risk Minimisation Measures and Definition – let's navigate together through the updates or Pharmacovigilance between MA application and approval – challenges for sponsors transforming to MAH

12:50 – 14:00 Network lunch

14:00 – 15:30 Practical Experience of Applying Artificial Intelligence in PV

15:30 – 16:00 Coffee break & networking

16:00 – 17:30 Audit & inspections



AIFA REFORM: WHAT IS IT AND WHO ARE THE NEW MEMBERS OF THE GOVERNANCE

AIFA, THE ITALIAN MEDICINES AGENCY, HAS RECENTLY EMBARKED ON A SIGNIFICANT REFORM: A PROCESS OF RESTRUCTURING GOVERNANCE TO PROMOTE INVESTMENTS IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT AND ACCELERATE DRUG APPROVAL PROCESSES. HERE ARE THE DETAILS.



WHAT IS THE AIFA REFORM?

The AIFA reform is a process of restructuring the agency's governance aimed at promoting investments in pharmaceutical research and development, in line with Mission 6 of the National Recovery and Resilience Plan (PNRR), and accelerating drug approval

processes by streamlining the regulatory framework. The process was initiated in November 2022 with [Decree Law No. 169](#) developed by the Ministry of Health, in conjunction with the Minister of Public Function and the Minister of Economy and Finance in agreement with the State-Regions Conference.

AIFA REFORM: WHAT CHANGES?

With the AIFA reform decree, the following operations have been implemented:

- Abolition of the General Director. To simplify the organizational structure, the figure of the General Director has been abolished. The President assumes the legal representation of AIFA and chairs the Board of Directors. They will be appointed by a decree of the Minister of Health, in agreement with the State-Regions Conference, and with the consent of the Minister of Economy and Finance. The role of President will be an exclusive appointment, prohibiting any other professional activity, both public and private. Since there are no new indications in the Regulation, specific skills are not required for the President, and the duration of their term remains five years with the possibility of renewal only once.
- Introduction of new managerial roles. Two new figures have been introduced that will take on some of the roles of the General Director.
 - Administrative Director. Responsible for administrative management, they will be appointed by decree of the Minister of Health, after consulting with the Minister of Economy and Finance and the State-Regions Conference. The Administrative Director must have a master's or specialist degree in legal or economic matters, or equivalent qualifications, along with proven professionalism and managerial experience. The duration of their term is five years with the possibility of renewal.
 - Technical-Scientific Director. Appointed by ministerial decree, following consultation with the Minister of Economy and Finance and the State-Regions Conference. The Technical-Scientific Director must hold a degree in health disciplines or equivalent qualifications, with technical-scientific experience in the pharmaceutical sector. The duration of their term is five years with the possibility of renewal.
- Abolition of the CTS and CPR in favor of the CSE. A key element of the reform is the creation of the Scientific and Economic Commission (CSE) to replace the Technical-Scientific Commission (CTS) and the Prices and Reimbursements Committee (CPR). The Drug Scientific and Economic Commission, appointed by the Minister of Health, is composed of ten members: the Technical-Scientific Director of AIFA and the President of the Higher Institute of Health, or their delegate, are ex officio members. Four members are appointed by the Minister of Health, one of whom will serve as president of the Commission, one member is appointed by the Minister of Economy and Finance, and three members are appointed by the State-Regions Conference. CSE members have a term of three years, renewable once.
- Modification of the Board of Directors. The composition of the Board of Directors undergoes significant changes. Following the reform, it consists of the President and four members, one appointed by the Minister of Health, one appointed by the Minister of Economy and Finance, and two by the State-Regions Conference.

WHO IS THE PRESIDENT OF AIFA?

Following the reform, the AIFA President is Robert Giovanni Nisticò. He takes the place of the previously appointed and immediately resigned Giorgio Palù. His mandate lasts five years, with the possibility of renewal once.

WHO MAKES UP THE NEW AIFA BOARD OF DIRECTORS?

The AIFA Board of Directors (CDA) is composed of:

- President Robert Giovanni Nisticò, appointed by the Minister of Health;
- Advisor Vito Montanaro, Director of the Health Promotion Department of the Region, appointed by the Permanent Conference for Relations between the State, Regions, and Autonomous Provinces of Trento and Bolzano;
- Advisor Angelo Gratarola, Regional Health Councilor of the Liguria Region, appointed by the Permanent Conference for Relations between the State, Regions, and Autonomous Provinces of Trento and Bolzano;

- Advisor Emanuele Monti, President of the Welfare Commission of the Lombardy Regional Council, appointed by the Minister of Economy and Finance.

The new AIFA Board of Directors took office on 20/03/2024 as [communicated by the agency](#).

WHO IS THE ADMINISTRATIVE DIRECTOR?

The Administrative Director is Giovanni Pavesi. He is an expert in healthcare management and general director of the Welfare Department of the Lombardy Region. He was appointed by Minister Schillaci (Ministry of Health). His term lasts five years, with the possibility of renewal.

WHO IS THE TECHNICAL-SCIENTIFIC DIRECTOR?

The Technical-Scientific Director is Pierluigi Russo. Previously the head of the AIFA Monitoring Registers Office, he now leads the technical-scientific direction. His term lasts five years, with the possibility of renewal.



WHO ARE THE MEMBERS OF THE CSE INTRODUCED BY THE AIFA REFORM?

The members of the CSE include ex officio the Technical-Scientific Director of AIFA, Pierluigi Russo, and the President of the Higher Institute of Health or their delegate. In addition to these, for a total of ten members:

- Lara Nicoletta Angela Gitto, professor of economics, appointed by the Minister of Health, serving as president;
- Giancarlo Agnelli, cardiologist and professor of Internal Medicine, appointed by the Minister of Health;
- Walter Marrocco, general practitioner, appointed by the Minister of Health;
- Vincenzo Danilo Lozupone, pharmacist, appointed by the Minister of Health;
- Ida Fortino, head of the Pharmaceutical Service of the Lombardy Region, appointed by the Minister of Economy and Finance;
- Elisa Sangiorgi, manager of the Drug and Medical Devices area of Emilia-Romagna, appointed by the Permanent Conference for Relations between the State, the regions, and the autonomous provinces;
- Giuseppe Toffoli, director of Experimental and Clinical Pharmacology at the Aviano Oncological Center, appointed by the Permanent Conference for Relations between the State, the regions, and the autonomous provinces;
- Giovanna Scroccaro, head of the Pharmaceutical Service of the Veneto Region, appointed by the Permanent Conference for Relations between the State, the regions, and the autonomous provinces.

Non-ex officio members serve a term of three years and are renewable only once.



STAGES OF THE AIFA REFORM

The long-awaited AIFA reform began in November 2022 and is expected to conclude in May 2024. Here are the stages:

November 2022: the Meloni Government initiates the reform of AIFA governance with Decree Law No. 1691.

November 15, 2023: the State-Regions Conference approves the AIFA reform.

December 1, 2023: the advisory technical-scientific committee and the prices and reimbursement committee, operating at AIFA, are abolished. Simultaneously, the Drug Scientific and Economic Commission is established, with its functions attributed.

December 14, 2023: the AIFA reform is definitively approved by Parliament.

January 15, 2024: ministerial decree of January 8, 2024, No. 3, containing the Regulation amending the organization and functioning of AIFA, is published in the Official Gazette.

January 30, 2024: entry into force of ministerial decree January 8, 2024, No. 3.

February 2, 2024: appointment of the ten members of the Scientific and Economic Commission.



February 6, 2024: Minister of Health Orazio Schillaci signs the decree containing the names of the members who will compose the new Scientific and Economic Commission.

February 8, 2024: appointment of the President, the Administrative Director, and the Technical-Scientific Director.

March 2024: appointment of the members of the Board of Directors.

April 2024: adoption of the Board of Directors' resolution on the functioning and organization of personnel and reshaping of AIFA's organic allocation.

May 2024: submission and approval of the resolution by the Ministry of Health.

WHAT TO EXPECT FROM THE AIFA REFORM

The AIFA reform, occurring almost twenty years after the establishment of the agency, represents a significant step towards a more functional and secure system. Through the reorganization of governance and the introduction of new managerial figures and advisory bodies, the Agency prepares to face future challenges more efficiently and effectively. The goal of promoting investments in research and pharmaceutical development, along with the acceleration of drug approval processes, promises to bring tangible benefits for both patients and healthcare professionals. It now remains to closely monitor the implementation of the reform and evaluate its impact on the landscape of Italian healthcare.

PHARMACOVIGILANCE: NEW FUNDS EXPECTED FROM AIFA'S BOARD OF DIRECTORS

THE NEW BOARD OF DIRECTORS RECENTLY ANNOUNCED THE ALLOCATION OF FUNDS FOR PHARMACOVIGILANCE AMOUNTING TO APPROXIMATELY 5 MILLION EUROS.



AIFA'S NEW BOARD OF DIRECTORS

The recent [AIFA reform](#) introduced a new Board of Directors. The Board took office on March 20, 2024, as [announced by AIFA](#), and consists of:

- Francesco Fera, Vice President and Counselor appointed by the Minister of Health;
- Emanuele Monti, Counselor appointed by the Minister of Economy and Finance;
- Angelo Gratarola e Vito Montanaro, Counselors, appointed by the Permanent Conference for Relations between the State, the Regions, and the Autonomous Provinces of Trento and Bolzano.

COMMITMENT TO PHARMACOVIGILANCE

During the recent inauguration of AIFA's new Board of Directors, it was announced, in agreement with the Regions, the commitment to finance projects on pharmacovigilance amounting to €5,051,397, along with the allocation of PNRR Funds for interventions to enhance corporate cybersecurity totalling €480,000.

The announcement of the investment in pharmacovigilance projects demonstrates the Agency's commitment to drug safety and surveillance processes.

AIFA LAUNCHES A NEW DIGITAL PLATFORM FOR THE MANAGEMENT OF PHARMACOVIGILANCE FUNDS

IN ITALY, THE MANAGEMENT OF PHARMACOVIGILANCE FUNDS WILL BECOME MORE EFFICIENT THANKS TO AIFA'S NEW PLATFORM. REGIONS WILL NOW BE ABLE TO BETTER MONITOR RESOURCES, IMPROVING THE SAFETY AND TRANSPARENCY OF PROCESSES.



THE AIFA'S PLATFORM FOR THE MANAGEMENT OF PHARMACOVIGILANCE FUNDS

Starting from October 1, 2024, the Italian Medicines Agency (AIFA) has made available a new digital platform for the management of pharmacovigilance funds, with the aim of

improving the efficiency and traceability of processes related to post-marketing monitoring of medicines. This tool is accessible to all Regions and represents a real breakthrough for Regional Pharmacovigilance Centers, facilitating smoother management of resources allocated to active surveillance projects.

A STEP TOWARDS DIGITALIZATION: EFFICIENCY AND CONTROL

The new platform replaces the previously used manual systems, which slowed down data collection and analysis. This shift to digital allows for the standardization of technical and financial data entry, simplifying the sharing and analysis of information. In this way, it will be possible to monitor each stage of the process, from funded activities to communications between various stakeholders, with continuous and automated control of deadlines thanks to integrated notifications and reminders.

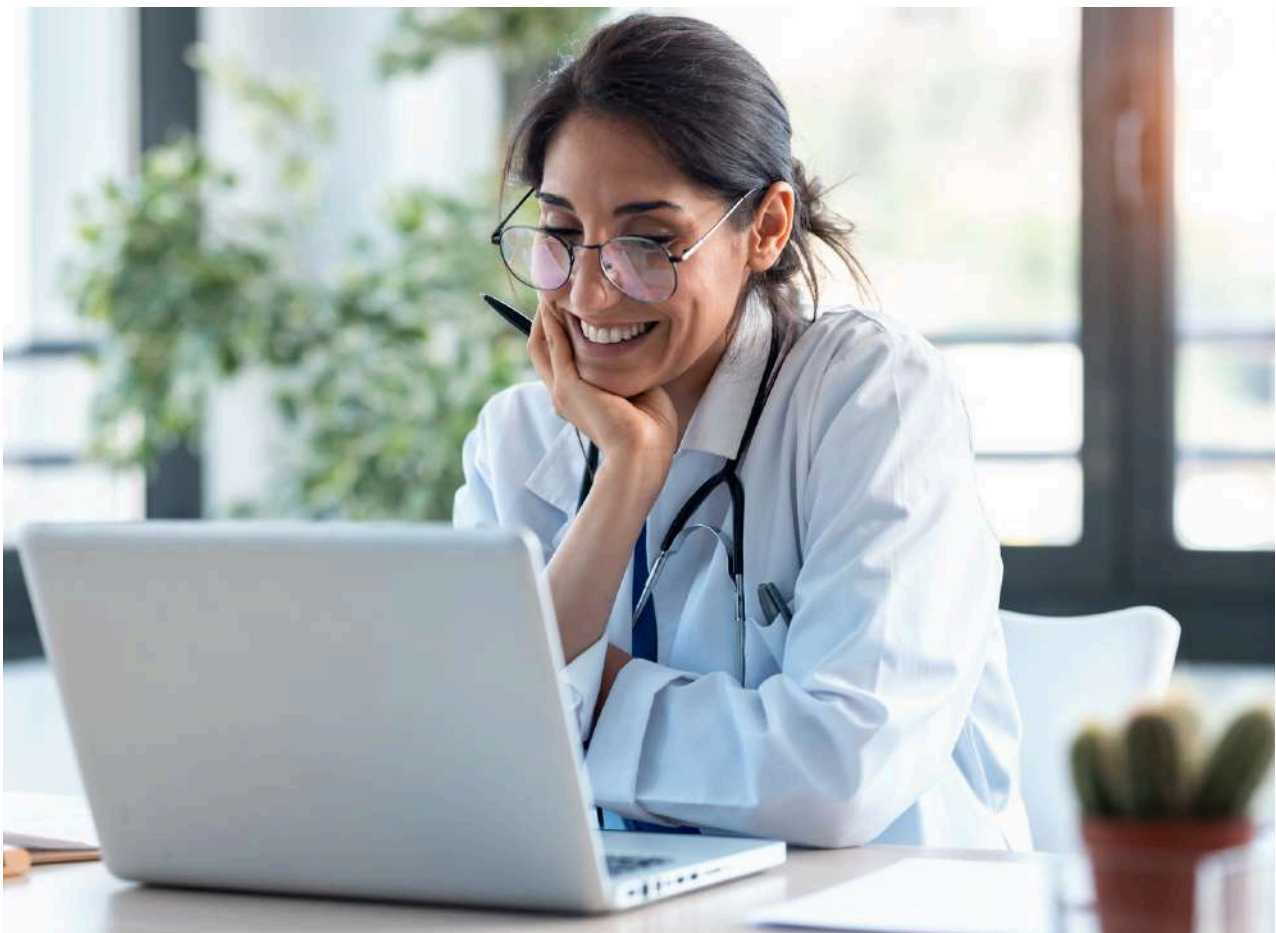
Anna Rosa Marra, head of AIFA's Post-Marketing Surveillance Area, emphasized how this tool will enable more efficient and transparent management of resources,

improving coordination between Regions and AIFA itself.

This will contribute to optimizing pharmacovigilance activities, ensuring more accurate control over the safety and proper use of medicines in real-world conditions.

AIFA PLATFORM: A SYSTEM SUPPORTING PUBLIC SAFETY

AIFA's new IT system has been designed to support the work of the Regional Pharmacovigilance Centers, which play a key role in post-marketing surveillance of medicines. Through continuous monitoring and optimized management of financial resources, the platform enables greater transparency and more precise control over funded activities, ensuring enhanced patient safety.



CLINICAL TRIALS: WHAT ARE THEY?

CLINICAL TRIALS ARE A FUNDAMENTAL PHASE IN THE DEVELOPMENT OF A THERAPY. THEIR IMPORTANCE LIES IN DETERMINING THE EFFECTIVENESS OF A TREATMENT BY COMPARING IT WITH OTHER AVAILABLE OPTIONS AND EVALUATING ANY POTENTIAL SIDE EFFECTS. TO MARK INTERNATIONAL CLINICAL TRIAL DAY, AIMED AT RAISING AWARENESS ON THIS TOPIC, WE HAVE GATHERED ESSENTIAL INFORMATION WORTH KNOWING ABOUT THEM.

WHAT ARE CLINICAL TRIALS?

Clinical trials, or clinical trials, are an important phase of scientific research in which tests are conducted on volunteer patients to evaluate the effectiveness and safety of a therapy. This treatment can involve drugs, medical devices, vaccines, and other medicinal products, including the use of diagnostic equipment.

In most cases, trials involve the safety and efficacy of a new therapy, but they can also investigate the administration methods or timing of an existing drug, protocols for early diagnosis of a disease, or lifestyle interventions for patients, such as specific diets or exercise programs.

Clinical trials can be promoted by companies (known as profit studies) or by groups, societies, associations, or independent individuals (known as non-profit studies), involving either a single research centre or collaborations among multiple centres, both nationally and internationally.

THE FIRST CLINICAL TRIAL

The first controlled clinical trial was conducted in 1747 by Dr. Lind, a ship's surgeon in the British fleet. Determined to find a cure for scurvy, a disease that decimated long-haul sailors until the mid-18th century, he conducted an experiment. He divided the sailors into groups of two and administered different preparations based on the knowledge of the time to each group. The pair of sailors who received a preparation based on oranges and lemons recovered from scurvy, unlike the others. This led to the discovery that scurvy was caused by a lack of fresh citrus in the diet, which provides vitamin C.

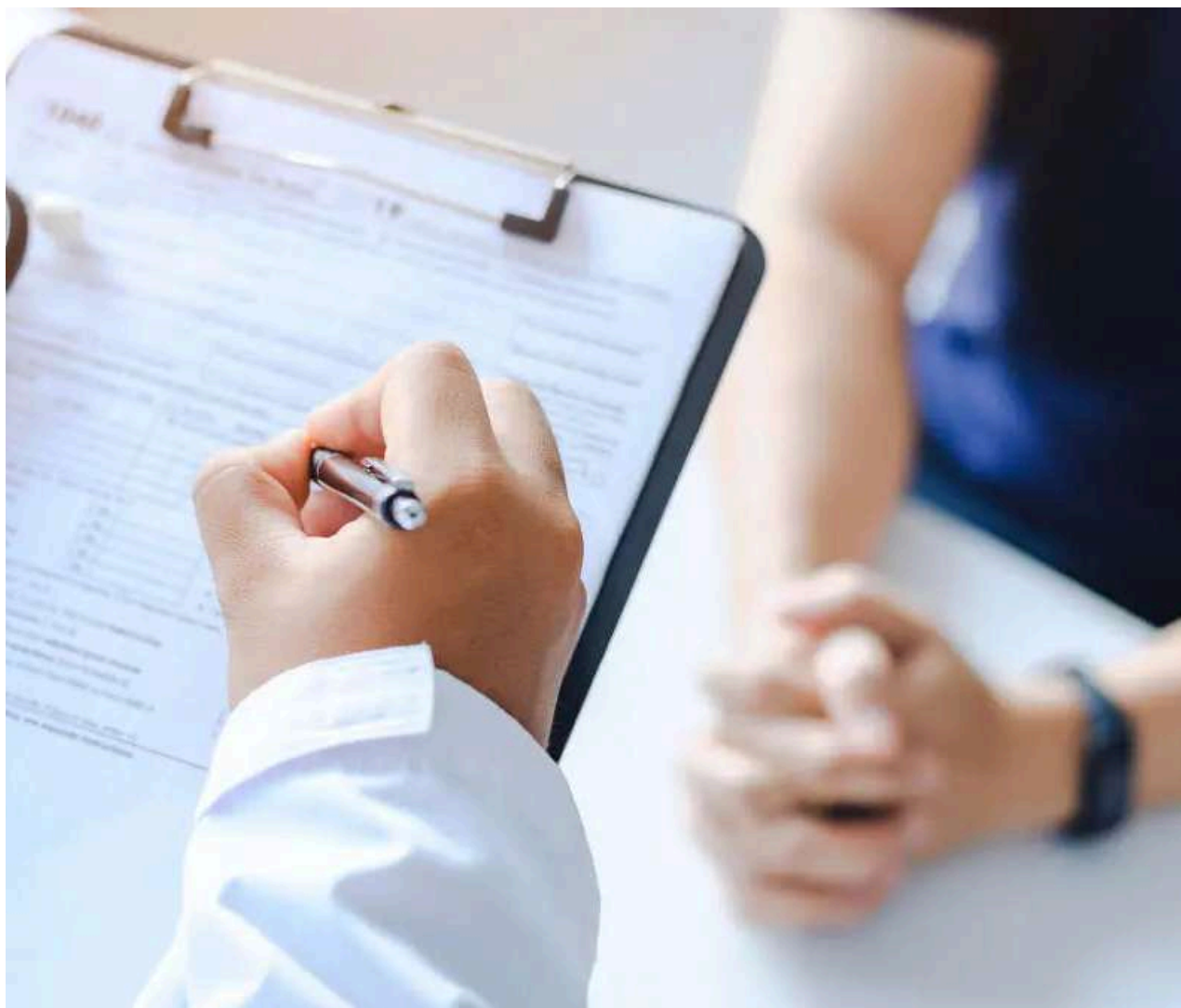


PRECLINICAL TRIALS

Today, times have changed: clinical research is much more advanced, and trials are more targeted. Before a new therapy can be administered to patients, it is essential to demonstrate the scientific hypotheses that led to its creation through rigorous controlled procedures and laboratory simulations. This preliminary phase, known as preclinical research, aims to provide evidence of the potential effectiveness of the treatment against the disease.

Preclinical studies, also known as preclinical trials, consist of tests conducted before administration to patients. These include in vitro tests conducted in the

laboratory on cells, including those taken from individuals affected by the disease, and in vivo tests involving the use of animals when reliable in vitro tests involving the use of animals when reliable in vitro tests are not available. During this phase, tests are also conducted to evaluate the chemical stability of the molecule and technical studies to define the formulation and optimal dosage for human application. The duration of preclinical studies extends on average for three to five years or more. If the preclinical tests yield positive results, the clinical trial phase, involving direct testing on humans, follows. About 50% of the tested molecules pass the preclinical tests.



PHASES OF CLINICAL TRIALS

The time required to conduct a clinical trial can be extremely prolonged, especially when testing a new drug. This is due to the need for caution and the need to carefully consider the peculiarities of the disease and its progression over time.

Some diseases have a chronic course with relapses over the years, making it inappropriate and risky to draw hasty conclusions about the effectiveness of a treatment.

Additionally, some drug side effects may only manifest after a long period. Therefore, it is sometimes necessary to follow patients for several years.

Clinical trials consist of four phases.

PHASE I OF CLINICAL TRIALS

Phase I of a clinical trial is dedicated to evaluating the action and safety of the drug under investigation. The drug is administered in progressively increasing doses, starting from the lowest possible dose to a very limited group of individuals, usually less than 80, most of whom are healthy volunteers, except in oncology studies.

The main aim of this phase is to investigate the tolerability of the drug, its pharmacokinetics, metabolism, and pharmacodynamics. It seeks to identify any side effects that may not have been evident during preclinical studies conducted on cells and laboratory animals, to determine the maximum tolerated dose.

It is important to note that Phase I is primarily aimed at obtaining knowledge and not at therapeutic purposes. It provides crucial information to establish analogies and differences with the data obtained during preclinical studies,

offering indications on future therapeutic activity and the appropriate dosage for human use. Phase I typically lasts about 1-2 years. If the results of this phase are positive and the drug is considered safe, the Ministry of Health and Regulatory Health Authorities may authorize the transition to Phase II, involving a larger sample of people. About 70% of drugs successfully pass this initial testing phase.



PHASE II OF CLINICAL TRIALS

Phase II of clinical trials is dedicated to evaluating the effectiveness of the drug and its short-term side effects. During this phase, a larger group of people is involved compared to Phase I, primarily consisting of patients rather than healthy volunteers.

The molecule is administered for the first time to the subjects for whom it was formulated. The number of participants can range from about 25 to 300, depending on the frequency of the pathology being studied.

The primary objective of this phase is to establish the minimum dose of the drug that has therapeutic activity against a particular disease.

About 33% of drugs pass this phase and advance to the next one. The results obtained from Phase II studies are submitted to global health authorities for

approval for commercialization. It is important to note that there is a risk in this phase that drugs with high therapeutic potential but intended for a small number of patients with rare conditions, known as orphan drugs, may be discontinued in the commercialization process.

PHASE II OF CLINICAL TRIALS

During Phase III of clinical trials, the evaluation of side effects and the risk/benefit ratio is carried out. Additionally, the molecule is compared with other standard therapies (or placebo if no treatment exists) to demonstrate and confirm the superiority of the new treatment over previous therapies. Different dosing regimens are also tested for commercialization, and potential interactions with other drugs are analyzed.

In Phase III studies, the effectiveness and safety of the treatment are evaluated on a large scale, involving a variable number of patients between 1000 and 3000. The selection of patients is extremely rigorous, aiming to ensure they are representative of the population affected by the disease, identifying the type of patient most suitable for the treatment, and excluding at-risk subgroups. These studies are usually conducted simultaneously at multiple sites, often internationally, in academic or hospital settings, following rigorous protocols. Phase III typically lasts 4-5 years. About 25% of drugs successfully pass this phase. The company that developed the drug can then apply for marketing authorization from competent authorities, such as the EMA for Europe. Subsequently, in Italy, the AIFA will evaluate whether the authorized drug can be reimbursed by the National Health Service.



PHASE IV OF CLINICAL TRIALS

Phase IV of clinical trials consists of monitoring the drug after its commercialization. Some side effects, even severe ones, may only manifest when the drug is taken by a large number of people in everyday practice. Therefore, it is crucial to continue monitoring the treatment by collecting information on the drugs and their potential long-term side effects. This phase is commonly known as pharmacovigilance and is essential for promptly identifying any problems related to the use of the drug and taking necessary measures to ensure public safety.

TYPES OF CLINICAL TRIALS

- Experimental studies. Also known as interventional studies or clinical trials. These studies aim to test the effectiveness and safety of a therapy through specific tests. Participants are required to take a particular treatment following precise rules.
- Observational studies. As the name suggests, these studies focus on long-term observation of diseases, exposure to a particular substance, or lifestyle to identify the benefit/risk ratio or potential improvement solutions. These studies are divided into:
 - Prospective studies. The patients involved are followed throughout the study to evaluate the intervention.
 - Retrospective studies. Events that occurred before the start of the study are investigated.



Additionally, based on the type of clinical question being investigated, there are the following types of clinical studies:

- Prevention studies. Useful for researching the best way to prevent a certain disease in healthy people or to prevent the disease from recurring.
- Screening studies. Essential for investigating the best way to detect certain diseases.
- Diagnostic studies. Conducted to find which tests or procedures are best for diagnosing a particular disease or condition.
- Treatment studies. Conducted to investigate the safety and effectiveness of a new treatment, or surgical/radiotherapy procedure, for a specific disease or condition.

WHO PARTICIPATES IN A CLINICAL TRIAL?

A clinical trial consists of:

- volunteer patients (or healthy volunteers for the first phase of clinical trials);
- the research team consisting of doctors, nurses, and other healthcare professionals;
- experts in statistics, data analysis, and informatics to analyze study results;
- the sponsor who funds the study.

A clinical trial can take place in hospitals, clinics, medical centers, universities.



THE CLINICAL TRIALS SPONSOR

Clinical trials can be funded by various sources, including pharmaceutical industries, foundations, scientific societies, and voluntary groups such as patient associations. Studies funded by research institutions or receiving public funding are called independent. Participation in this type of clinical trial can offer benefits such as evaluating long-term risks or rare adverse effects of treatments, comparing different therapeutic options, and verifying improvements in daily life.



However, many clinical trials are sponsored by the pharmaceutical industry and aim to demonstrate the efficacy and safety of new treatments for regulatory approval. Knowing who funds a clinical trial is essential to understand the study's objectives and make informed decisions. Conflicts of interest can arise when researchers receive financial compensation from pharmaceutical companies interested in the ongoing study. These conflicts should be declared and carefully evaluated to ensure the objectivity and integrity of the clinical trial.

WHAT IS A STUDY PROTOCOL?

Clinical trials result from a complex organization involving various professionals and require careful coordination between research teams at national and international levels. Before the study begins, a plan, known as a study protocol, is defined. This protocol details all aspects of the study, including

- research purposes and objectives;
- valuation criteria;
- inclusion and exclusion criteria for patient selection;
- the clinical test e their frequency;
- the therapeutic plan, that is the modalities and the administration period of the experimental drug;
- the involved centres.

This protocol provides detailed guidelines for all aspects of the study, ensuring rigorous standardization and allowing for an accurate evaluation of the results obtained.

WHO UNDERGOES CLINICAL TRIALS

Clinical studies involve voluntary patients who are carefully informed about the type of experimentation they will undergo. Depending on the nature of the study, volunteers may be individuals with specific conditions or certain characteristics.

In the initial phase of studies on a new drug, aimed at examining potential toxicity and identifying the maximum tolerable dose, healthy volunteers without pre-existing medical conditions may also be involved. However, for ethical reasons, healthy volunteers will not be administered treatments that could be toxic, such as oncological drugs.

CONDITIONS INDICATING THE RELIABILITY OF A STUDY

A clinical study is considered reliable when it is controlled, randomized, and at least double-blinded. The presence of all these conditions ensures the study's rigor.

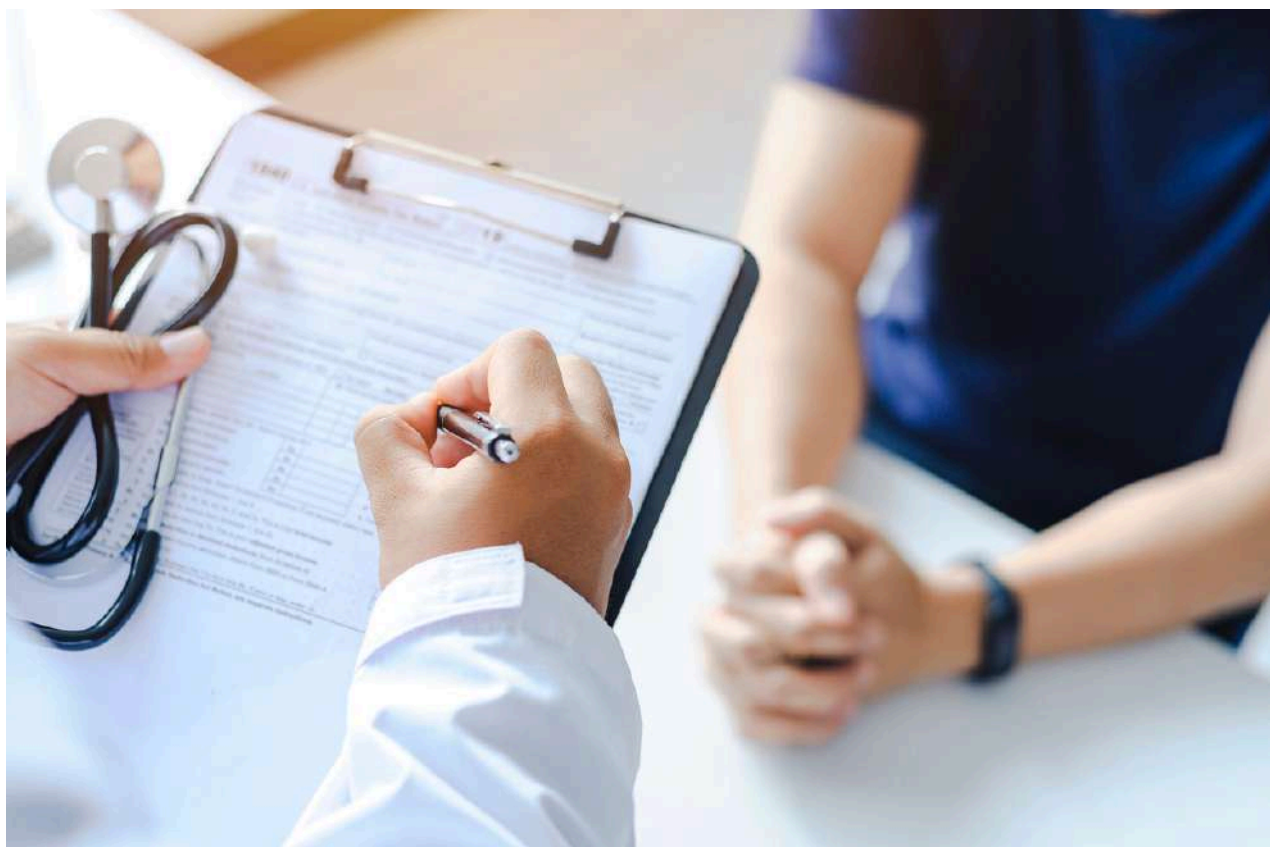
CONTROLLED STUDY

A controlled study involves dividing patients into two distinct groups. One group will receive the experimental treatment, while the other group will receive standard treatment or a placebo, which is a formulation without an active ingredient. The second group is termed the control group. All other conditions of the study, including examinations and clinical checks, will be uniform for all volunteers. This approach makes it easier to identify differences caused by the type of treatment administered, thus ensuring an accurate comparison between the two groups.

RANDOMIZED CLINICAL STUDY

In randomized clinical studies, two types of drugs are compared. Therefore, participants are divided into two distinct groups, and each group is assigned one of the two drugs under study. This assignment occurs randomly to avoid any interference in the results and to ensure that there is no bias in the selection of treatments. This way, each participant has an equal chance of receiving the experimental treatment.

Randomized clinical trials represent the gold standard in clinical research, especially when evaluating the effectiveness of an innovative treatment. However, it is not always possible to conduct a randomized clinical study due to factors such as financial issues, lengthy timelines, or ethical reasons.





BLIND OR MASKED STUDY

A clinical study is masked when it is not known which drug a particular patient is taking. The masking conditions can vary:

- Single-blind or single-masked study: the patient does not know which of the comparison drugs they are taking and may receive a placebo.
- Double-blind or double-masked study: neither the patient nor the doctor knows which treatment is being administered.
- Triple-blind or triple-masked study: in addition to the patient and the doctor, the data analyst is also unaware of the patient's group assignment, ensuring an impartial assessment of the results.

Masking is essential to prevent influences on the judgment of results, ensuring that observations of both negative and positive treatment effects are objective.

If all treatment information is known, the study is referred to as open-label.

CHARACTERISTICS OF A RELIABLE CLINICAL STUDY

The characteristics of a reliable clinical study are fundamental to ensuring the integrity of the research and the safety of the participants. In summary, these characteristics include:

- **Ethics:** The clinical study must be designed and conducted with the aim of improving and innovating in the treatment of medical conditions. All decisions made during the study must be guided by ethical principles that prioritize the well-being of the participants.
- **Independence:** The study must be independent and free from conflicts of interest. It must solely address the needs and safety of the participating patients and must not be influenced by commercial, academic, or career interests.
- **Transparency:** All research results must be made public and accessible. This includes not only positive results but also negative or neutral ones. Transparency is essential to ensure that the scientific community and the public can accurately assess the study results.
- **Approval:** The clinical study must be pre-approved by an independent ethics committee. Additionally, participants in the study must be aware of the risks and benefits of the study and must provide their informed consent before participating.

Before initiating a clinical study, it is important to carefully evaluate whether there is a real need for research, whether there is uncertainty about the effectiveness of the new treatment compared to existing ones, and whether the study design is adequate to address specific research questions. This pre-evaluation helps ensure that the study is scientifically valid and ethically acceptable.

THE RISKS OF PARTICIPATING IN A CLINICAL STUDY

Participating in a clinical study can entail some risks that are crucial to fully understand before making a decision. Among the main risks is the fact that desired treatment outcomes cannot be guaranteed, and in a randomized study, the patient cannot choose which treatment to receive. Additionally, it may be necessary to commit a significant amount of time to visits, tests, and hospital stays, and there may be exposure to unknown risks since the new treatment has not been extensively tested and some adverse effects may not have been identified yet.

However, it is important to remember that clinical studies are conducted and supervised by highly qualified doctors at centers of excellence. Patients are carefully monitored and undergo regular follow-up visits to promptly identify any complications or side effects.

THE BENEFITS OF PARTICIPATING IN A CLINICAL STUDY

Clinical studies represent a crucial decision for those affected by an illness. Participating in a clinical study can mean gaining access to innovative and potentially effective therapies for one's medical condition. Additionally, the patient involved in the study undergoes regular visits and tests, ensuring constant monitoring of the disease and their health status.

Another important aspect not to be overlooked is that participating in a clinical study involves actively contributing to the development of fundamental knowledge that can improve the daily fight against human diseases. Personal contribution to medical research can not only bring direct benefits to the participating patient but can also positively influence the future treatment of patients with similar conditions worldwide. It is an act of altruism and solidarity that can have a significant impact on the health of many people.

HOW TO PARTICIPATE TO A CLINICAL STUDY

Participating in a clinical study typically starts with a recommendation from the treating physician, who provides the patient with all possible information through a written document called an informed consent form. This document describes in detail the study's objectives, the planned tests and checks, possible side effects, benefits, and risks. It is up to the patient to decide whether or not to participate in the study, and signing the informed consent form is not binding to conclude the trial: at any time, a volunteer can suspend their participation in the study.

Increasingly, especially abroad, patients themselves, individually or through patient associations, actively seek clinical trials related to their disease, often via the internet. For this purpose, public registries of clinical studies have been created, online databases developed by research centers, scientific associations, and government agencies, listing ongoing or upcoming trials for a specific disease or condition.



WHO TAKES CARE OF THE PATIENT DURING THE CLINICAL TRIAL?

During a clinical trial, the patient is entrusted to experienced and competent medical and paramedical staff within authorized hospital facilities, university research centres, or private institutions. This team will take care of the patient throughout the duration of the clinical trial, also requiring their active collaboration. For example, the patient may be asked to keep a diary to record specific data or any symptoms experienced during the trial. They may also be requested to complete questionnaires or provide regular feedback on their health status and the treatments received. The medical staff, on their part, will need to record any adverse events in specific safety databases, such as SafetyDrugs, in order to analyze their progression and evaluate the safety of the experimental therapy.



Furthermore, the medical team will continue to follow up with the patient even after the conclusion of the clinical trial, providing continuous assistance and support. Physicians, nurses, and other professionals involved in the study will be available to provide clarification and assistance at any time, both during and after the clinical trial, to both the patient and their family.

The period of observation during which the patient undergoes clinical and diagnostic tests is called the follow-up. This

observation period allows for the evaluation of the effectiveness of the experimental treatment over time.

LAWS AND GUIDELINES FOR PATIENT PROTECTION IN CLINICAL TRIALS

To ensure the protection of patients participating in clinical trials, various international and national laws, as well as ethical codes, have been enacted. Among these important regulations, we find:

- The Helsinki Declaration. This document lists the fundamental ethical principles that must be respected in medical research involving human subjects. The Declaration emphasizes the principle of informed consent, the need to maximize benefits and minimize harm to patients, and the importance of independent and ethically approved review of clinical trials.
- The Oviedo Convention. This Council of Europe convention establishes rules and principles regarding human rights and human dignity in medical and biological practices, including free and informed consent and the protection of patients' personal data.
- Good Clinical Practice (GCP). These are international guidelines that define standards for the design, conduct, recording, and reporting of clinical studies involving human subjects. GCP focuses on ethics, scientific quality, and participant safety in clinical trials.

These regulations and guidelines provide an ethical and legal framework for the conduct of clinical trials, ensuring that patients are treated respectfully, their rights are protected and the information obtained from the studies is reliable.

THE ROLE OF THE ETHICS COMMITTEE

The role of the Ethics Committee is crucial in ensuring the protection of patients involved in clinical trials. This independent body is composed of a variety of qualified professionals, including physicians, patient representatives, ethics experts, pharmacologists, and statisticians, who carefully evaluate every aspect of the clinical study.

The Ethics Committee meticulously reviews all documents related to the study, including data collection forms, informed consent, and data privacy policies. Its primary priority is to protect the rights, safety, and well-being of study participants, and this consideration must prevail over any other interests, including those of science and society.

Depending on the assessment, the Ethics Committee may provide a favorable, unfavorable, or suspensive opinion. It may also request modifications to the study protocols to ensure greater patient protection. Obtaining the favorable opinion of the Ethics Committee is an essential requirement for initiating a clinical trial, confirming that ethical standards and patient safety have been adequately considered and respected.

IN WHICH WAYS IS THE PATIENT ACTIVELY PROTECTED?

The patient in a clinical trial is protected in several ways. Firstly, protocol approval is required: a clinical trial cannot include patients if the protocol has not been approved by the competent authorities and the Ethics Committee.

Moreover, before deciding whether to participate or not, the patient will be provided with all the information about the study in writing in the informed consent. Once the informed consent is signed, researchers are obliged to follow it scrupulously. The patient has the right to contact the Ethics Committee for any doubts or concerns and can withdraw from the study whenever they want.

Also, in terms of privacy, the patient is protected. Data will remain confidential and will not be included in the clinical trial report.

Lastly, the sponsor of the clinical trial is required to provide insurance to patients in case of adverse events.





ROLES IN CLINICAL TRIALS IN ITALY

Clinical research in Italy involves various actors, each with specific and complementary roles.

AIFA, the Italian national competent authority. Responsible for authorizing clinical trials and amendments to various phases. It plays a coordinating and directing role on all aspects related to experimental drugs, including safety and efficacy monitoring.

ISS, the Italian national Institute of Health. Provides advisory opinions on clinical trials, especially for phase I trials. It contributes to the scientific evaluation and approval of clinical trials, ensuring special attention to participant safety.

Ethics Committees. Operate within healthcare facilities where clinical trials

take place. They assess the ethical merit of studies, ensuring they conform to good clinical practice standards and respect the rights and well-being of participants.

General directorates of healthcare facilities. Responsible for defining contracts and administrative management of clinical trials within healthcare facilities.

Promoters and Researchers. Directly involved in the organization and conduct of individual clinical trials. They are responsible for study design, data collection and analysis, and communication of results.

EMA with its EudraVigilance database. Handles reports of serious and unexpected adverse reactions (SUSARs) during the conduct of clinical trials. It contributes to monitoring the safety of experimental drugs.

PROMOTING AWARENESS OF CLINICAL TRIALS: THE ECRAN PROJECT

The ECRAN (European Communication on Research Awareness Needs) project is a European Union initiative aimed at promoting knowledge and awareness of medical research among European citizens and making it more accessible and understandable. To achieve these goals, ECRAN has developed a series of educational and informational materials available in 23 European languages. These materials include a [website](#), [FAQs](#), and other educational content. All these tools are designed to provide clear and accessible explanations of both basic and advanced concepts in medical research, overcoming linguistic and cultural barriers.

Furthermore, ECRAN is committed to providing accurate and objective

information about the benefits and risks of clinical trials, encouraging informed and aware participation by citizens. Through awareness-raising and education, the project aims to actively engage European citizens in medical research, thus promoting health and societal well-being.

INTERNATIONAL CLINICAL TRIALS DAY

May 20th is International Clinical Trials Day. It is an important initiative aimed at raising public awareness of the importance of clinical research in promoting health and improving disease treatments. This day offers an opportunity to reflect on the challenges and opportunities of clinical research and to celebrate the progress made through clinical trials. For more information and to participate in International Clinical Trials Day initiatives, visit the [official website](#).



MEDICAL DEVICES: WHAT CHANGES WITH THE AI ACT?

WITH THE ENTRY INTO FORCE OF THE AI ACT, NEW RULES ARE ESTABLISHED FOR MEDICAL DEVICES BASED ON ARTIFICIAL INTELLIGENCE (AI). HERE ARE THE IMPLICATIONS FOR PHARMACEUTICAL COMPANIES REGARDING SOFTWARE AS MEDICAL DEVICE (SaMD).

WHAT IS THE AI ACT?

The AI Act, officially known as the EU Artificial Intelligence Act, is a regulation of the European Union (Regulation EU 2024/1689) that aims to establish a regulatory framework for the use of artificial intelligence (AI) within the EU to ensure safety, transparency, and compliance with fundamental rights.

This regulation was proposed by the European Commission on April 21, 2021, and approved by the European Parliament on March 13, 2024. The law came into effect on August 1, 2024, marking a significant step in the regulation of AI globally.

The regulation defines global requirements for the design, production, and marketing of AI systems to ensure safe and ethical use in highly regulated sectors such as healthcare. This new act particularly impacts Software as a Medical Device (SaMD), introducing a new level of responsibility for manufacturers, healthcare service providers, and regulatory bodies.



WHICH SOFTWARE IS CONSIDERED A MEDICAL DEVICE?

According to the MDR, a software falls into the category of a medical device (Software as Medical Device – SaMD) if it meets three criteria:

- it has a specific intended use related to the diagnosis, prevention, or treatment of diseases;
- it processes complex data, producing relevant outputs for medical purposes;
- it is used on humans to generate diagnostic or therapeutic information.

The increasing complexity of software, especially those using AI, presents new challenges. Specifically, the integration of AI requires that SaMD also comply with the new AI Act regulations.

WHAT IS ARTIFICIAL INTELLIGENCE ACCORDING TO THE AI ACT?

The AI Act defines artificial intelligence as “an automated system designed to operate with varying levels of autonomy and that may present adaptability after dissemination and that, for explicit or implicit objectives, deduces from the input it receives how to generate outputs such as predictions, content, recommendations, or decisions that may influence physical or virtual environments.” This definition is crucial for determining when a SaMD integrates artificial intelligence and must therefore comply with the application rules of the AI Act.



WHEN DOES A SaMD NEED TO COMPLY WITH THE AI ACT?

SaMDs fall under the scope of the AI Act if they exhibit the following characteristics:

- variable autonomy: the software can learn from different areas, such as computer vision, natural language processing, voice recognition, intelligent decision support systems, and intelligent robotic systems;
- adaptability: the device can evolve through direct interaction (with inputs and data) post-market release;
- definition of objectives:
 - explicit, set by humans, or implicit, from training data;
 - implicit, deriving from rules specified by humans;
 - not fully known in advance (recommendation systems using reinforcement learning to gradually narrow the model of individual user preferences);
 - related to generating outputs such as recommendations, predictions, and decisions.

Therefore, a SaMD falls under the application of the AI Act if it integrates AI with learning and adaptation capabilities. This pertains to systems capable of evolving post-commercialization, which use algorithms to make complex clinical decisions. If a SaMD is based on AI, it must comply with both the MDR and the AI Act, integrating the two regulations to ensure safety and regulatory compliance.

RISK CLASSIFICATION IN THE AI ACT

The AI Act introduces a regulatory framework that classifies artificial intelligence systems based on the level of risk assessed in terms of the probability and severity of negative impacts on people's and society's rights. The risk can be: minimal (not regulated by the AI Act), limited, unacceptable and high. Each category requires different control and compliance measures.

Limited risk. Refers to AI systems that do not pose a significant danger to safety, fundamental rights, or the health of individuals. Examples of limited-risk AI include chatbots. These systems require only minimal transparency requirements; thus, users must be clearly informed about how the AI operates and makes decisions, allowing users to make informed choices.



Unacceptable risk. Relates to AI systems that violate fundamental human rights or threaten safety. These systems include, for example, subliminal or manipulative techniques that influence human behavior without awareness, exploit personal vulnerabilities such as age or disability, use social scoring to unfairly discriminate against individuals or groups, profile crime risk solely on a predictive basis, or deduce emotions and personal characteristics from biometric data in unauthorized contexts. Such systems are deemed non-compliant for reasons of safety and protection of fundamental rights and are therefore prohibited by the AI Act.

High risk. Concerns AI systems that can significantly influence the health, safety, or fundamental rights of individuals. This includes systems intended to provide information used to make decisions for diagnostic or therapeutic purposes or to monitor physiological processes. In this case, there are additional obligations for users and manufacturers, including the requirement for evaluation by a Notified Body.



HIGH RISK: IMPLICATIONS FOR INDUSTRY OPERATORS

If the Software as Medical Device based on AI is considered high risk (whether as a safety component of another product or as a stand-alone product), both the manufacturer and user must comply with the obligations of the AI Act.

Manufacturers are required to demonstrate compliance with the new regulations by involving a Notified Body for safety and quality verification. They must adopt and implement risk assessment and management processes, as well as provide detailed documentation on the operation of AI systems. They must also ensure ethical use of data and fulfill post-marketing monitoring, correction, and information obligations regarding the system's operation.

Users of AI-based medical devices must be aware of the legal responsibilities associated with using such technologies. This involves adequate staff training to correctly use the system, constant monitoring of the AI system, and following operational protocols to prevent errors or malfunctions. They must also adhere to safety standards, maintain transparency, and document any issues related to the use of the device, managing any risks proactively.

Additionally, Notified Bodies must acquire specific expertise to assess AI systems and ensure compliance of high-risk AI systems before they are placed on the market. Providers and importers must ensure compliance with EU regulations, and distributors have the obligation to verify that suppliers comply with regulations and may have liability in case of non-compliance.



AI ACT: KEY IMPLEMENTATION DATES

The AI Act, effective from August 1, 2024, has a phased implementation schedule with key milestones:

- February 2, 2025: Entry into force of Chapters I and II of the AI Act. Chapter I promotes a human-centered and trustworthy AI to protect health, safety, and fundamental rights. It also requires the education of providers and deployers in AI risks. Companies must ensure that their staff, and anyone involved in operating AI systems, receive adequate training. Chapter II describes prohibited AI systems deemed dangerous. These include real-time biometric recognition technologies, which must cease to be marketed or used.

- May 2, 2025: Deadline for completing codes of good practice, which will help companies comply with the AI Act guidelines.
- August 2, 2025: Entry into force of Chapter V, applying governance rules and obligations for general-purpose AI systems, along with the enforcement of sanctions.
- August 2, 2026: Full application of the AI Act. All high-risk AI systems must comply with the regulation. Companies will need to establish control systems and implement effective monitoring plans to continue operating in compliance.
- August 2, 2027: Final deadline for SaMD classified as Class IIa, IIb, and III to conform to the AI Act.

The regulation is scheduled for review by August 2, 2028, and every four years thereafter.



RALLY LANA 2024: 37TH EDITION FULL OF THRILLS

THE RALLY LANA 2024 TOOK PLACE ON JULY 19 AND 20, ATTRACTING DRIVERS AND ENTHUSIASTS FROM ALL OVER THE WORLD TO BIELLA. ONCE AGAIN, SAFETYDRUGS RENEWED ITS ROLE AS THE OFFICIAL SPONSOR OF THIS PRESTIGIOUS EVENT.



RALLY LANA: A STORY OF PASSION AND COMPETITION

The Rally della Lana is a prestigious car race held annually in the Biella area, which has become a must-see event for motorsport enthusiasts. Its first edition was held on April 14, 1973, when Franco Perazio, driving his Fulvia H.F. 1.6 Gr4, inaugurated the competition in front of an excited crowd. Initially conceived as a "Regolarità Sprint" race, the rally quickly gained fame, establishing itself as one of the toughest challenges in the Italian Rally Championship.

Over the years, the race has attracted top-tier drivers like Gianni Besozzi, Bossetti, Carello, and Dalla Pozza, who have helped elevate Rally della Lana to an international level. In 1978, the competition was promoted to "International Rally," marking a significant milestone in its growth.

In the 1980s, the management of the rally was taken over by a team of experts, including "Meme" Gubernati, Roberto Bologna, Federico Ormezzano, and Renato Genova, with the support of Dante Salvay. In 1984, the organization was handed over to Biella Corse, further strengthening the event's reputation.

During the 1990s, drivers such as Piero Longhi and Andrea Dallavilla kept the competition in the spotlight with their consecutive victories. The new millennium saw the participation of international figures like Jean Ragnotti, Patrick Snijers, and Harry Toivonen.

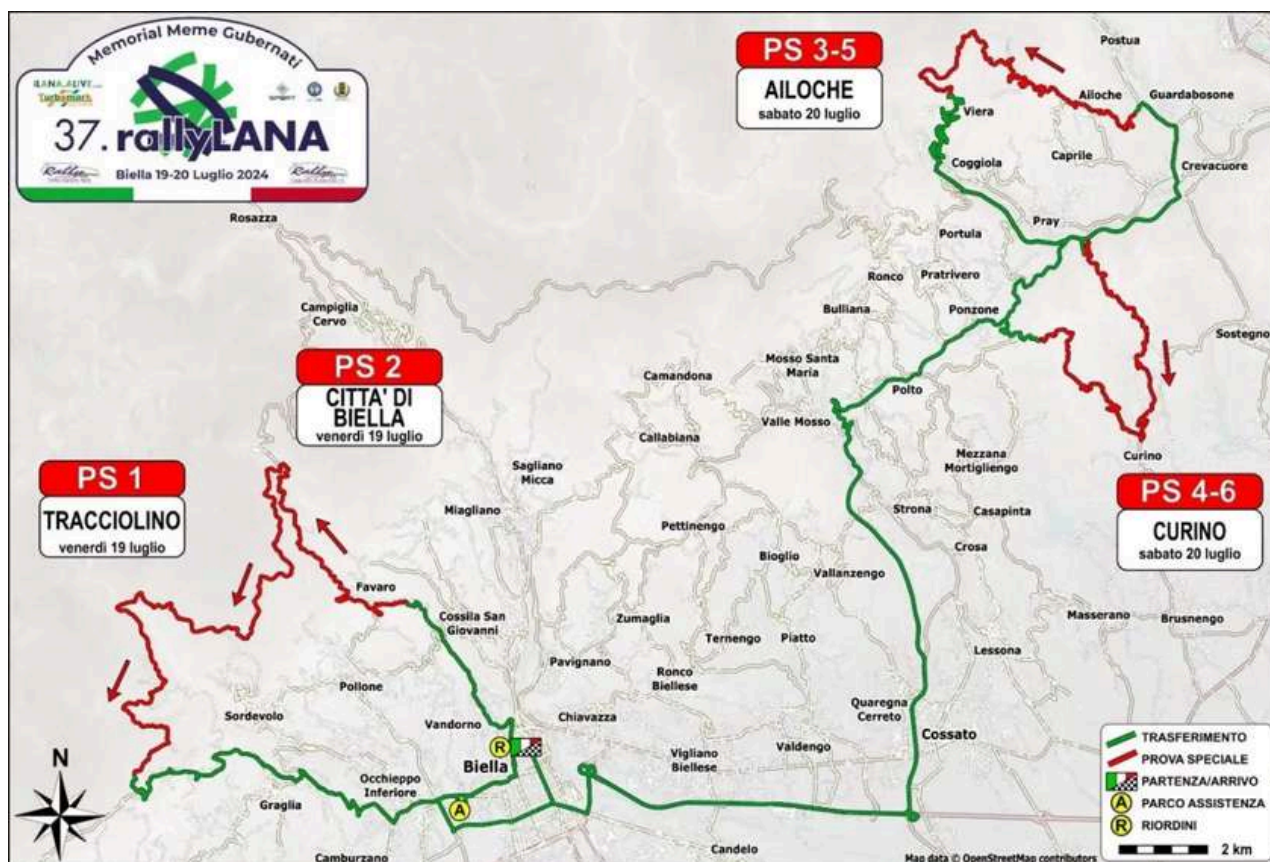
After a hiatus, the Rally della Lana returned in 2018 thanks to the efforts of "Rally Lana Alive" and "New Turbomark," continuing to offer a technical and challenging course. The comeback edition saw brothers Ivan and Marina Carmellino take the victory.

With over 40 years of history, Rally della Lana remains a highly anticipated event, where tradition and innovation come together to offer a unique experience for both drivers and spectators.

RALLY LANA 2024: RACE ROUTE

The route of Rally Lana 2024 once again lived up to the tradition of one of Italy's most iconic races. It passed through some of the most breathtaking landscapes of the Biella area, featuring technical and spectacular sections that challenged the drivers' skills. The selected roads offered a thrilling experience for spectators, with demanding curves and high-speed straights.

The total course covered over 400 km, with approximately 110.75 km of special stages, making this edition one of the most challenging and spectacular ever.





RALLY LANA 2024: THE PROGRAM

Day 1: Friday, July 19

Start: The race began at 17:31 in Piazza Martiri della Libertà in Biella.

- SS 1 “Tracciolino”: Starting at 18:30, this 16.17 km special stage posed an immediate challenge, with a variety of road conditions requiring intense focus.
- SS 2 “Città di Biella”: At 22:01, the drivers faced the long 23 km stage, which included the ascent to the Santuario di Oropa. This night stage added extra difficulty and excitement.

Day 2: Saturday, July 20

- SS 3 and SS 5 “Ailoche”: The “Ailoche” stage took place in two sections, the first at 10:10 and the second at 13:25. This 11.50 km stage featured narrow roads and abrasive surfaces, with downhill sections requiring careful management of tires and brakes.

- SS 4 and SS 6 “Curino”: Spanning 13.12 km, “Curino” is a historic and technical stage, also run in two phases—the first at 10:46 and the second at 15:01. This year, the stage was run in the reverse direction compared to 2022, adding a new layer of challenge.

The final finish took place at 16:01 in Piazza Martiri della Libertà, with the awards ceremony concluding the event.

WHO WON THE RALLY LANA 2024?

The Rally della Lana 2024 saw an all-Skoda podium, with Mattia Pizio and Luca Simonini taking first place. Ivan Carmellino and Elio Tirone finished second, followed by Elwis Chentre and Massimiliano in third. The race was marked by an unexpected twist, as local favorite Corrado Pinzano was forced to retire due to a technical issue.

PIGIAMA RUN 2024: JOIN US FOR LILT'S CHARITY RUN

THE PIGIAMA RUN IS A CHARITY RACE ORGANIZED BY LILT (ITALIAN LEAGUE FOR THE FIGHT AGAINST TUMORS) TO SUPPORT CHILDREN WITH CANCER. EVEN IN 2024 WE SUPPORTED THE CAUSE.



WHAT IS THE PIGIAMA RUN?

The Pigiama Run, organized by LILT (Italian League for the Fight against Cancer), is an event created to raise funds to support the families of children with cancer. It consists of a march or run in which participants wear pyjamas, a symbol of closeness to the young patients who spend long periods in hospital. This year it will be held on September 20, 2024 at 6:30 pm, starting from 40 LILT locations throughout Italy.

GOALS ACHIEVED AND CURRENT CHALLENGES

The 2023 edition saw enthusiastic participation, with over 12,000 people running in various Italian cities, raising a total of €400,000 for support projects for children with cancer and their families. In Biella, home of SafetyDrugs, the race attracted 1,100 participants and raised €18,850. Thanks to these funds, LILT was able to provide shopping vouchers to the families of young patients, but also launch the Alveare Amico project, an initiative that aims to offer comprehensive support to the families of children and young people with cancer in the area. The goal is to respond to the practical and psychological needs of families, providing them with assistance in many ways: from psychological support to guidance on available services, through the organization of adapted physical activities for children in recovery. The project also includes transportation services to off-site healthcare facilities, bureaucratic support and leisure opportunities for patients and their families. Alveare Amico represents a concrete response to improve the quality of life of those who face such a difficult challenge.

OUR COMMITMENT TO THE PIGIAMA RUN 2024

We have proudly renewed our support for the Pigiama Run. As a company specializing in the development of pharmacovigilance databases, SafetyDrugs, we work every day to help ensure the safety of drugs and we understand the importance of improving the lives of those facing serious diseases. Participating in events such as the Pigiama Run is a concrete way for us to give back to the community, not only through our technical expertise, but also with tangible support for the most vulnerable families.

We have therefore participated both as a sponsor of the event, to support the organization and implementation of the event at a local level, and as active participants in the race to make a concrete

contribution to supporting the families of children with cancer.

The Pigiama Run 2024 took place in 40 Italian cities including Milan, Rome and Turin, with the ambitious goal of reaching 25,000 participants and exceeding the 500,000 euro fundraising needed to consolidate the new project.

Also, for all the participants of the Pigiama Run 2024 we have created a playlist with motivational songs to face this important race with energy. You can find it here or by scanning the code below.





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