



icpm 20th International Conference on Pharmaceutical Medicine
Hybrid Meeting 19-21 October 2022 SNFCC, Athens - Greece

What lies ahead in Pharmaceutical Medicine

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INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE



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ICPM 2022 – Meet the Speakers

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What lies ahead in Pharmaceutical Medicine

Trends Reigniting Biomedical Research & Disruptive Technologies, Accelerating R&D and Advancing Clinical Medicine.

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ROUND TABLE - DAY 1





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October 19, 2022 MAIN HALL - HYBRID 15:00-16:30 Round table: "THE IMPACT OF THE EUROPEAN CLINICAL TRIALS REGULATION ON GLOBAL CLINICAL DEVELOPMENT"	Ingrid Klingmann	MD, PhD, Chairman at EFGCP, President at PharmaTrain Federation, Managing Director at Pharmaplex	Clinical trials expert, Science Policy and Regulatory Affairs, EFPIA	<Silvia Garcia
	CEO of IPPOSI, Ireland	<Derick Mitchell	EMA Head of Department for Access to Document	<Anne Sophie Henry-Eude

SESSION - DAY 2

October 20, 2022 MAIN HALL - HYBRID 12:30-13:30 Session: "RWD TRENDS IN PHARMACOEPIDEMIOLOGY AND OPPORTUNITIES FOR RWE"	Brigitte Franke-Bray			<Elena Panitti	Xavier Kurz
	Johannes Pleiner-Duxneuner			<David Brown	

ROUND TABLE - DAY 3



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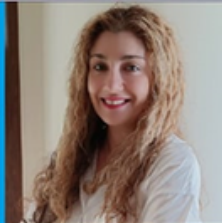
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October 21, 2022
MAIN HALL - HYBRID
11:30-13:00

Round table:
"ARTIFICIAL
INTELLIGENCE AND
MODERN TRENDS IN
PHARMACOVIGILANCE
AND ACTIVE SAFETY
SURVEILLANCE"

<Georgia Gkegka>



<Christina
Tsougkou



<Pantelis
Natsiavas



<Karthick
Sukumaran

[CHECK ICPM 2022
PROGRAMME](#)

OCTOBER 19TH-21ST, 2022

20th International Conference on Pharmaceutical Medicine



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System Requirements for the National Individual Electronic Medical Record (National EMR) for Use in Clinical Trials in Greece

Usage Scenario by EL.E.F.I. Hellenic Society of Pharmaceutical Medicine

Access to the patient file is necessary in conducting clinical trials to establish Source Data Verification (SDV). SDV confirms that the data collected for the clinical trial in the Electronic Data Capture (EDC) System agree with what is mentioned in the patient's medical record. A process known as Source Data Review (SDR) confirms that the data follow the ALCOAC (Attributable, Legible, Contemporaneous, Original, Accurate and Complete) principles. These processes are requirements in the context of Good Clinical Practice and are mandatory in European legislation under the European Medicines Agency (EMA) Regulation 536/2014.



Until March 2020, the data monitoring process in Greece was done exclusively on site, using the printed hospital patients' records at the study site.

During the COVID-19 pandemic, due to lockdown conditions, it became necessary to proceed with SDV and SDR remotely, where possible. The health systems that already had certified electronic patient records could implement this important step in conducting clinical trials by remotely accessing and monitoring the data of study patients.

EMA has issued relevant instructions since 2010 which are constantly updated since.

The value of a National EMR is critical for the Greek National Health System. We strongly suggest that National EMR additionally takes into account the specifications necessary for its use as source documentation in clinical trials, so that Greece remains current in conducting clinical trials in the future, given that clinical research and drug development is a global process and obeys international standards and guidelines of regulatory authorities, such as the European Medicines Agency (EMA), the FDA/USA, MHRA/UK and of course, the Greek National Medicines Agency (EOF).



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International Laws and Regulations

- [Regulation \(EU\) No 536/2014 of the European Parliament and of the Council of April 16, 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC](#)
- [WHO - Guidance on Good Data and Record Management Practices, Annex 5](#)
- [FDA - 21 CFR Part 11](#)
- [FDA - Guidance for Industry, Data Integrity, & Compliance with the cGMP](#)
- [EMA - Guideline on computerised systems and electronic data in clinical trials \(draft\)](#)
- [MHRA - GxP Data Integrity Definitions and Guidance for Industry](#)
- [EudraLex – Volume 4 GMP Annex 11 General](#)
- [OECD - Application of GLP Principles to Computerised Systems Advisory Document 17](#)
- [ICH - Efficacy Guidelines GCP E6 - Electronic Systems](#)
- [PIC/S Guidance, Good Practices for Computerised Systems in GxP Environments](#)
- [PIC/S Guidance, Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments](#)
- [GAMP Records and Data Integrity Guide](#)



Special Considerations:

In order for the National EMR to be used directly as a "source document" in the context of clinical trials, it must satisfy the specifications below:

1. The clinical trial monitor (CRA) should have controlled access with personal passwords, limited capabilities (read only) and specific terms, that are documented in a written confidentiality agreement, binding compliance with the requirements of the General Regulation on Personal Data Protection (EU GDPR 2016/679).
2. In practice, the user (site staff or monitor) should be able to have the additional option of remote access to data from a computer via the Internet under certain conditions.
3. The study patient visits should be identified, fully recorded and include all the necessary data of medical history, clinical appearance, clinical assessment findings and diagnostic tests at least in a text description.
4. Dictation software would be very helpful in order to avoid further recording burden for site and study staff.
5. The system should ensure that the clinician-investigator certifies the finalisation of the patient's data in his/her electronic file with a certified electronic signature with legal validity.
6. The National EMR should clearly state that the specific patient is participating in a specific clinical trial, at a specific site, in case the patient visits a doctor external to the study site, so that the doctor can record any events or possible side effects and contact the study site in case of an emergency.



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7. The system should be fully traceable (audit trail), with backup capability, controlled access and good practice certification (GxP) *.
8. The system should have a detailed user manual, which, among other things, will determine user training and will be reviewed periodically.

The use of the National EMR will also support the efforts of the research centres participating in clinical trials by facilitating patient identification and selection at study sites.

The application of the above basic requirements is necessary for the simultaneous use of the National EMR in clinical studies for SDV and SDR purposes. In this way, we will ensure that Greece will remain competitive in the field of clinical research and will have taken a first step toward digitisation and innovation by collecting reliable data, more efficiently. Our next steps should be to examine whether the National EMR can function in the future as an electronic sources (e-source) for the immediate, thorough and reliable collection and analysis of data.

K. Papageorgiou, V. Vazeou, A. Mavraki, A. Aletra, V. Baroutsou **EMR Clinical Trials Working Group**

EL.E.F.I. Clinical Research & Clinical Trials Innovation Forum

*In the life sciences industry, GxP is **an abbreviation referencing the various “good practice” regulations and guidelines that apply to organisations that manufacture products that are consumed or used by humans or animals.** This includes medical, cosmetic, tobacco, products or devices and food products.



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Medical Information in Pharmaceutical Industry

16es Jornades Catalanes d'Informació i Documentació
25 - 27 May 2022



MEDICAL INFORMATION IN PHARMACEUTICAL INDUSTRY Development and Implementation of a University Expert Course

Elena Guardiola¹, Lurdes Cabo², Elena Molina³, Patricia Ortega⁴, Ángela Flores⁵, Sylvaine Balmy⁶, Nuria Escudero⁴, María-Ángeles Hernández⁷, Mónica Rojo⁸

01 Medical Information in Pharmaceutical Industry

The pharmaceutical industry (PhI) is an important provider of medical information and scientific documentation. Medical Information (MI) is a necessary activity which allows medicines and devices marketed by the PhI to be used in a safe and effective way. It is a function that provides precise, updated and objective information to healthcare professionals, patients and other relevant decision makers or regulatory authorities who may require it¹.

A variety of professionals, with different profiles, especially graduates in health sciences and in information and documentation work in MI departments in the PhI. The needs for training of each of these profiles involved in the MI is inherently different.



02 Detection of a need

During the years 2015² (N=81) and 2019³ (N=44), the Medical Information Working Group (MIWG) of AMIFE (Spanish Association of Medicine of Pharmaceutical Industry) run two surveys on the structure of these MI departments between professionals of different pharmaceutical and biotechnological companies in Spain.



Nearly 60% of respondents to the 2019 survey said that their company did not have a specific MI training program; similar results were obtained in 2015 (65%).³

The handling of scientific information and the knowledge of pathology and company's products were the skills most valued by the professionals surveyed.

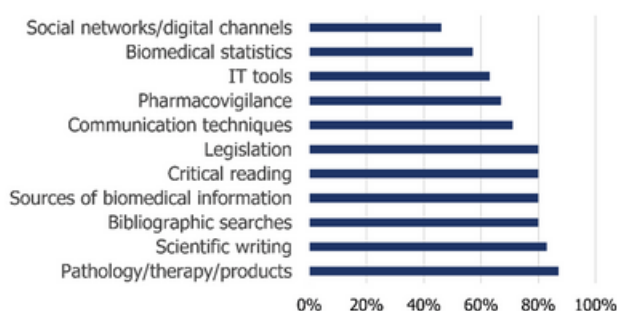
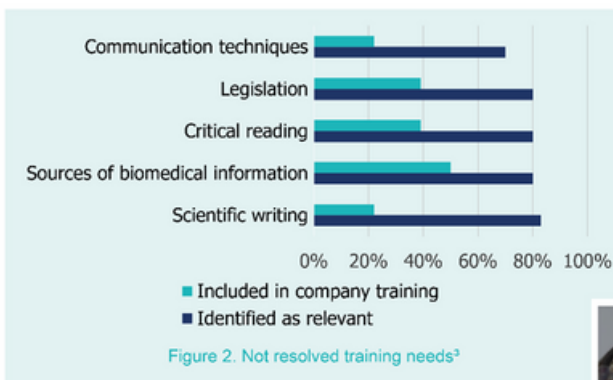


Figure 1. Training needs of MI departments



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Other unresolved training needs were detected in companies that did not have a training program.

"...MI specialists require specific training plans to fill the gap in disease knowledge, evidence understanding, communication skills, and social media."³



03 Development of the solution

The MIWG of AMIFE, composed by 36 members of 32 different companies, in collaboration with the University CEU San Pablo (Madrid), has developed the first postgraduate course in Spain focused only on MI in PhI⁴

Course addressed to graduates in information and documentation, interested in the field of health information; to graduates and students of the last courses of health and experimental health sciences, and to professionals of other departments of the pharmaceutical industry.

Possibility, for members of MIWG and their teams, to register in separate modules (modules 4, 5 and 6).

Table 1. Program of the first University Expert Course in MI in PhI (AMIFE and University CEU San Pablo)⁴

1. Context of MI	Organization and structure of PhI – MI in PhI – Departments and professionals
2. Activities of MI	Handling of medical inquiries, revision of promotional materials, relationship with pharmacovigilance
3. Legislation/regulations	Spanish and international law, deontology, compliance, copyright, personal data protection, good practices
4. Tools and sources in MI	Bibliographic databases, high quality bibliographic searches
5. Analysis of information	Critical reading, meta-analysis, real-world data
6. Creation and management of contents	Medical information letters, FAQs, content for digital channels, medical writing, content management software
7. Communication of information	Efficient, oral and written communication
8. Quality management	Indicators, metrics, audits and inspections
9. Value and future of MI	Value for companies and society and future challenges
10. Training period	Possibility of a 3-month internship in MI department of various PhI

04 Results of the 1st edition of the Expert Course in Medical Information in Pharmaceutical Industry



COURSE

- February – May 2022
- 100 hours of formal classes (12 weeks, 24 credits)
- Face-to-face and online
- 3 days/week, 5:30 pm to 8:30 pm
- Optional training period (min. 3 months) in MI departments of PhI



TEACHERS

- 14 professionals of MIWG of AMIFE
- 13 external experts of recognized prestige

STUDENTS

Complete Course (20)	Modules (11)
<ul style="list-style-type: none"> • 12 active professionals in PhI • 3 professionals of scientific consulting companies • 1 documentalists in a research center • 4 recently graduated (1 physician, 1 biologist, 2 pharmacists) 	<p>Some students have signed up for more than one module:</p> <ul style="list-style-type: none"> • 2 in the Tools and sources in IM module • 3 in the Creation and management of contents module • 10 in the Analysis of information module
<ul style="list-style-type: none"> • 14 in Madrid • 3 in Barcelona • 3 outside Spain (2 in Italy, 1 in Belgium) 	
<ul style="list-style-type: none"> • 4 students applied for internships 	



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05 Conclusions

MI in PhI is a specialized professional role, closely related to information and documentation but with very specific training needs. That is why specific training courses are very important for the excellence of the MI service.

The Expert Course in Medical Information in Pharmaceutical Industry offers a possibility of training in MI in the PhI unique in Spain.

The profile of students enrolled in this course, mainly active professionals in PhI, confirms the training needs not covered in MI in Spain, identified in the two surveys conducted previously by the MIWG^{2,3}.

Affiliations: ¹Bayer Hispania S. L., ²Sanofi, ³Amgen S. A., ⁴Meisys, ⁵Lilly, ⁶Laboratorios Borron, ⁷Gilead Sciences, ⁸Grünenthal España.

References: 1. AnisGlobal. Medical Information role in the Pharmaceutical Industry - White Paper. 2. Flores A et al. (2015) Descriptive analysis of Medical Information departments within the pharmaceutical industry in Spain. 9th Annual European Medical Information and Communications Conference and Exhibition. London 10-11th November 2015. 3. Flores A et al. (2021). A survey on the structure, organization, and functions of medical information departments in the pharmaceutical industry in Spain. *Professional of the Information*, 30(3). <https://doi.org/10.3145/epi.2021.may.10>. 4. Universidad CEU San Pablo. Curso de Experto en Información Médica en la Industria Farmacéutica.



Latest Publication of the IFAPP Ethics Working Group



Published on 16 September 2022 members of the IFAPP Ethics Working Group expanded on the need to develop ethics and situationally adaptive clinical research guidelines for the continuation of clinical trials in times of war. The full paper can be accessed [here](#).

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The continuation of clinical trials in times of war: A need to develop ethics and situationally adaptive clinical research guidelines

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KEYWORDS

research ethics, human rights, international humanitarian law, protection of vulnerable study participants, research integrity, adaptive design

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Two Years Later: A Look Back, Part 3

In this three-part series, Marlene Llópiz looks at how the pharmaceutical world was affected by the COVID-19 pandemic

(This is the third in a three-part series looking at the impact of the COVID-19 pandemic on the pharmaceutical industry. Read Part 1 in [IFAPP TODAY number 25](#) and Part 2 in [IFAPP TODAY number 26](#).

Management strategies can only be effective if you are willing to hold your employees accountable to their agreements, and if you are willing to hold yourself accountable to the agreements you make.



Photo by Marlene Teresa Llópiz Avilés

No matter what?

Even if we're living through a severe pandemic?

Build on Trust

Relationships built on trust are developed as managers and employees keep their commitments and successful results are achieved. Did employees pull together? Burnout and mindfulness and resilience became household words. Trust, respect, and accountability are not just buzzwords that you read in a mission statement. They are ideals to live by; without them, your management strategy cannot work (and neither can your business). The pharmaceutical companies held tight on trust – from every level of employment. Now more than ever, all had to be committed. Two years is a long time but time enough to have overcome the obstacles, the changes in rapport, the delays, the inconveniences, etc.

The Rules of the Game Changed

We never knew this would last this long. The culture changed and the industry had to go a long way toward creating a new company culture that people continued to be attracted to and fulfilled by.

In times of difficulties, heartaches, deaths, sickness – how does the company respond? COVID has affected many. I remember when it seemed so far-fetched and no one in my family had reported having the infection. And now? It seems odd that someone wouldn't have contracted the disease – whether fully vaccinated or not.

During COVID, we have had to create a working environment in which there are no surprises. No surprises for managers focused on coordinating the work of people who are all contributing to a given deadline or overall company objective.

No surprises for your employees, who naturally want to do something according to the rules and just as naturally are resistant and resentfully frustrated when the rules are changed without their knowledge due to an unknown and frightening situation like the pandemic.



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And no surprises for your customers, who come to you again and again with expectations that the positive experience that brought them back will be repeated.

COVID was surprise enough!

Who was/is involved (within and surrounding) the pharmaceutical industry?

There is no place for ambiguity. All hands on deck were required: vast collaboration from researchers, biologists, virologists, economists, engineers, statisticians, psychologists, etc. There are so many people behind the scenes we aren't aware of.

What else did the pharmaceutical industry do? It created an environment for well-attended online conferences, telephone calls, writing articles, training webinars and courses. But it also provided epidemiological surveillance, genome sequencing, vaccine development, and greater scientific knowledge in a blink of an eye. Never has science seen pharmaceutical development occurring so quickly and so efficiently.

It formed and created focused teams, developed working groups, established social media platforms, avoided rapid and unorthodox channels of communication – told us when information was fake news and pushed for truthful scientific productivity.

Not only were in-office staff members limited regarding contact with each other but production plants also had back-logged due to limited supplies and a lack of distribution mechanisms in this new realm. Because we depend on medications and devices as everyday consumers, there was often a loss of being able to purchase common drugs used. This in itself, in addition to not leaving our homes because we were scared of getting infected with the virus, contributed to not being adequately treated.

Two years have passed and we are slowly returning to “normality,” although we can still be surprised by new viral variants. Great progress has been made – testing is common ground for all – authorized kits are available for home use, face masks have become a part of our daily ensemble, and vaccines are moving to a more scheduled requirement. We're now up to a recommended second booster for those 50 and older in certain cases.

Will we go back to the way we used to live? Will the pharmaceutical industry be the same?

Normality in the future will never be what and how we lived in the past. The pharmaceutical industry has now shifted its interest to vaccine development, device production for more precise detection of the virus and switched to designing treatments for viral infections. It now seems all viral infections are in everyone's pipeline.

Over 50,000 articles have been published on COVID-19 in the last two years – only to make us realize the amount of scientific production worldwide. Pharmaceutical companies are now conducting research worldwide – their focus has changed dramatically in search of a betterment of our lives beyond COVID-19. In certain cases, and instances, the pharmaceutical companies have come together and worked in a team effort to combat worldwide diseases.



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If we all pull together and recognize that this is the time to put health first, above all other considerations, we can overcome this difficult and challenging moment.

The World Health Organization (WHO) continues to encourage individuals to take care of their own health and protect others by:

- washing hands frequently with water and soap or using hand-sanitizing gel;
- maintaining social distancing (keeping a distance of 1.5 meters between yourself and anyone else, especially those who are coughing or sneezing);
- avoiding touching your eyes, nose and mouth;
- following respiratory hygiene (covering your mouth and nose with your bent elbow or tissue when you cough or sneeze, then disposing of the used tissue immediately);
- seek medical care early if you have a fever, cough and difficulty breathing; and
- stay informed and follow advice given by your healthcare provider, national and local public health authority, or your employer on how to protect yourself and others from COVID-19.

This doesn't seem to be over yet. Let's not let down our guard. It may be a while until we are really freed from this turmoil.

This pandemic exposed the fragility and faults in each layer of our lives – from our innermost circle of family and friends to the nation state at the periphery.

We all switched to:

- staying at home;
- limited border controls – no traveling;
- strict hygiene campaigns;
- provided accessible testing;
- contact tracing – a history of contagion. We were/are still being watched. Epidemiology does that.

Everything has changed:

- we were given the power of owning our time, or were we?
- we required emotional support – we were closed in for months – no socializing, no contact;
- we needed and established interdependence – online and by several means of communication;
- we lost physical contact;
- we were socially isolated/distanced;
- we were forced to wear a mask;
- we became part of vaccination training campaigns;
- we provided care and resources to vulnerable community members, etc.

However, for every bleak future, there's a hopeful one. We know that taking care of others is taking care of ourselves.

Are we over COVID-19? We haven't finished vaccinating the world. We aren't done yet.



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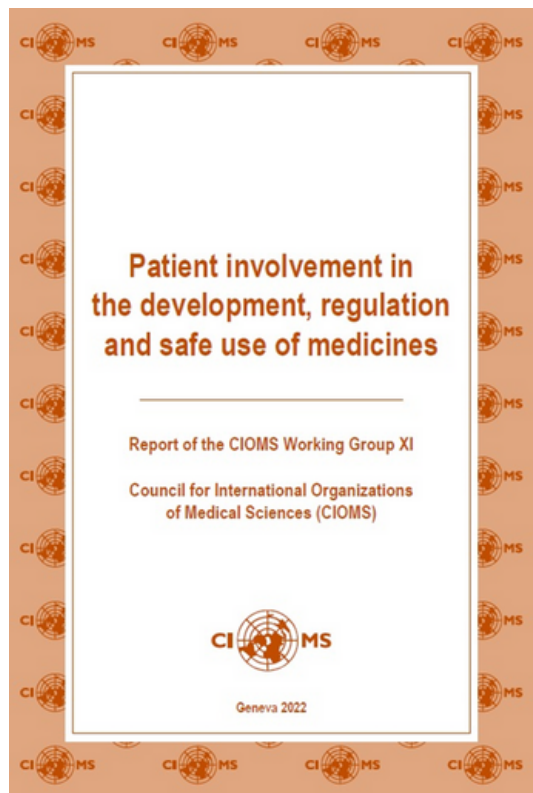
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Patient Involvement in the Development, Regulation, and Safe Use of Medicines



On 6 September 2022 the Council for International Organizations of Medical Sciences (CIOMS) launched the report of its Working Group (WG) XI (<https://doi.org/10.56759/iiiew8982>) under this title. The report consisting of 11 chapters and 5 appendices describes and promotes the idea that patients should be involved throughout the medicine's life cycle – from their development, through regulation to ongoing monitoring and safe use in everyday healthcare. It describes where we are, and a path to where we need to go. Many people and organisations work closely together to make sure that each medicine is fit for purpose. This involves long research to develop medicines that will meet regulatory authorities' stringent requirements for quality, safety, and efficacy. For as long as a medicine is used, it is important to keep monitoring its effects and especially any new side effects, and this is how some very rare side effects are identified. It is important that patients' views are taken on board throughout the medicine's lifetime – from development to product retirement. The development of a medicine is a complex and lengthy process.



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In the context of the report, when 'patients' are referred to, a wider group of people than just those taking the medicines is meant. The patient community also includes the patient's family, caregivers, patient organisations, and patient representatives.

The report underlines, that opportunities to involve patients start with a proper engagement to find out what type of medicines are needed. Only patients – who live every day with their health condition – can really say what causes them the greatest problems and what benefit of a medicine they value most. However, even though this is an obvious idea, it is still often overlooked. This makes it so important to engage patients at the very start of developing treatments. Then, for as long as a medicine continues to be used, patients can help to detect any new effects of the medicine. This builds up a fuller picture of the medicine's benefits and risks. Engagement with patients can be achieved by working with relevant patient organisations – some of which came out of patient activism movements. The barriers to overcome for successful patient engagement include legislative and regulatory burdens as well as language and communication obstacles. Above all, there needs to be a cultural shift to see patients more as partners in the development, regulation and safe use of medicines.

Very important are the principles for involving patients. Patients know best how their condition affects them. To make such involvement fair, sustainable and ethical, patients should be properly reimbursed for their time and expenses – and taking part should be made as convenient as possible. In this way they can play their full part. Patients' and patient organisations' independence should be maintained. It is most important that there is an open, trusting, long-lasting, and respectful relationship with patients. Clear communication is vital for the relationship, for example, digital technology can support communication and enable telemedicine.

Patients, and those who wish to involve patients, should have appropriate training, where necessary, to get the best out of this involvement. The training can involve: a) medicines-related sciences; b) ethics of health-related research; c) clinical trial methodology and interpretation; and d) medicines legislation and regulation. Patient organisations can offer, support and coordinate training. In addition, training is needed for all other stakeholders on how to best involve patients.

Patients should be involved in providing input into research on candidate medicines. They can work closely with healthcare professionals, academics and pharmaceutical companies on: a) defining the research goals and what treatment benefits to look out for; b) involving patients in clinical trials planning and design; and c) circulating emerging research information that it is clear, relevant, and timely. Patients' input in setting up and running clinical studies can improve the quality of the studies. Patients should also be involved in the design of a medicine and have a say on how it is formulated and packaged. The research programme should explore patients' perspective on their medical conditions and on the treatment (or prevention) of these conditions through well-designed 'patient preference studies'. These studies can help identify what factors patients consider important and relevant. This type of research is particularly valuable when there are many treatment options and also when opinions vary between people.



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When licencing medicines, regulators should continue to increase patients' involvement in decisions on assessing the benefits and risks of medicines and continuous monitoring for new information on their side effects. In some parts of the world, patient representatives are members of formal scientific and decision-making committees. They are also part of working groups on specific scientific aspects of medicine regulation. This trend must continue.

A lot of information is routinely collected in day-to-day medical practice – it is called 'real-world data'. To get most value from this, patients, health professionals, industry and regulators need to work together. Programmes called 'patient-centred initiatives' give patients the chance to provide their health information for research. Patients must be fully involved in planning and decisions on how real-world data are collected, stored, managed and released. Patients must also be involved in making sure their privacy is protected. Once a medicine has been approved for use, it is the patient-facing information – mostly the patient information leaflet - that provides patients with the 'official' information on how to use the medicine, what precautions to take, and what its side effects might be. This information can also help healthcare providers and patients during shared decision-making. Patient involvement in designing and drafting this information can improve its relevance, clarity and, above all, take-up of the advice. Patients provide important context about how the information is used. They can provide information on local customs and traditions, health literacy, and healthcare structures. Patients should also be involved in developing regulations on how such information for patients is produced and evaluated.

The usual information given to patients about a medicine might not be enough for some medicines – where there are certain risks. In such cases, additional risk minimisation measures for a medicine are needed. These may include the patient having regular tests or the need to take extra care over the use of certain medicines. Because these measures often create an extra burden on patients, they should be involved in decisions about the design of the measures. Sometimes there is the need for urgent safety communication after a medicine has been licensed. This may be about a new concern over the use of a medicine or a group of medicines. This information is usually for healthcare professionals – but sometimes it may need action from patients. Involving patients in setting up the process for such communication can make sure that patients' needs have been taken into account. Specifically, they can help to decide what issues need urgent communication, which groups of patients need to be informed, and how the information can be designed for patients.

Clinical practice guidelines describe how medicines should be used in day-to-day healthcare. The patient perspective is important in these guidelines, and patients should be involved in guideline development – by sharing their views and experiences. This is important because the benefits that patients think most important – and their acceptance of risks – may be different from what healthcare professionals think. Just as with medicine research and development programmes, it is possible to involve patients at many points in developing guidelines. This allows the guidelines to consider patients' needs and the recommendations will therefore reflect patients' goals from treatment. The guideline developer's goals and resources will determine how patient and public involvement is put into practice.



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There are many barriers to patient involvement – such as lack of opportunity and training, inconvenience, time commitment and financial outlay. These barriers are even greater in low- and middle-income countries. Patients in these countries also have additional problems of poverty and high level of disease; less developed regulatory and healthcare infrastructure; and low health literacy. In these countries, patient involvement can be improved by encouraging local research and development initiatives and working closely with international institutions and patient organisations. Also, involvement can be improved by raising health literacy – and by training health providers to look upon patients as partners in the delivery of healthcare.

Patient involvement in pandemics like the HIV pandemic, the SARS-CoV-2 pandemic has highlighted the scope of patient engagement to improve outcomes. The ongoing pandemic has given patients the chance to become involved at all stages of medicine and vaccine development and their use in practice. Some specific concerns have come to light, including: a) lack of knowledge on how new medicines and vaccines are developed; b) dealing with misinformation; c) quickly identifying and addressing public concern about vaccination; d) providing comprehensive information for patients to make an informed decision on vaccination; and e) making robust preparations for future pandemics.

In conclusion, the report describes the issues around the involvement of patients throughout the life journey of medicines. It gives many examples and recommendations to improve patients' participation in matters that ultimately affect their own health. Its added value is also a very comprehensive glossary with more than 90 terms and definitions. The report is a good reference to make best use of the many good practices described in it. This helps to continue improving engagement of patients in the development, regulation, and safe use of medicines.

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COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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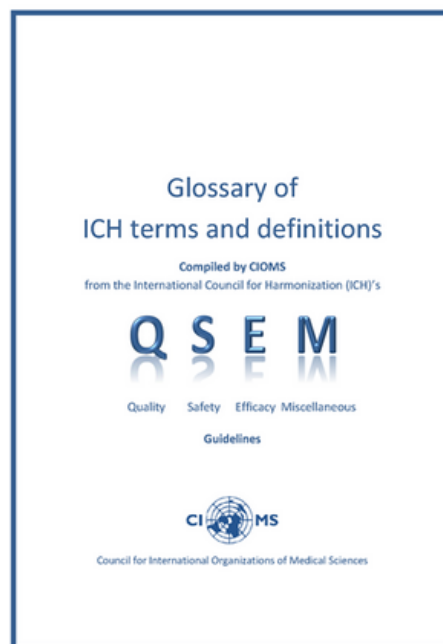
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Glossary of ICH Terms and Definitions and Cumulative Glossary with a Focus on Pharmacovigilance, Version 2.0

This is to announce a new CIOMS publication: the Glossary of ICH terms and definitions. CIOMS has compiled this glossary from the publicly available guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as a service to our followers, ICH stakeholders and other interested parties. The ICH Quality, Safety, Efficacy and Multidisciplinary guidelines reflect an international consensus on the scientific and technical aspects of drug registration. The ICH Secretariat has commended CIOMS for this helpful initiative.

To produce this resource, we have reviewed 121 ICH guidelines and Q&A documents posted on the [ICH website](#). We found a total of 1080 definitions, which are shown alphabetically in the Glossary along with the ICH guideline number, title, and where in the document the definition was found. This is followed by a list of the ICH documents reviewed, with a direct link to each one.



The Glossary of ICH terms and definitions is freely available for download here:

<https://doi.org/10.56759/eftb6868>

Please also take note of the Cumulative Glossary with a focus on Pharmacovigilance, Version 2.0, which you can find here: <https://cioms.ch/publications/product/cioms-cumulative-pharmacovigilance-glossary/#description>

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News from AMIFE

Around 100 people participated in the “Encounter – Presentation of the Working Groups of the Spanish Association of Pharmaceutical Medicine (AMIFE)” where different projects within the work areas of the pharmaceutical medicine were presented and the Coordinator, Antonio Gonzalez, commented the activities developed by the Working Groups. AMIFE’s President, Dr Isabel Sanchez Magro and the Vicepresident, Dr Susana Gomez Lus, made an acknowledgment on behalf of all the members of Anna Jurczynska for her years of dedication and selfless work for AMIFE.



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Click [here](#) for more information and registration.



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