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The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

Evolving Use of AI-Assisted Medical Writing in Clinical Research – Are We Treating the Hallucinations?

Regulatory medical writing has evolved over the past 30 years with the advent of stringent regulatory frameworks, standardised operating procedures, practical guidance and useful tools from leading professional medical writing societies, associations and pharmaceutical organisations. These include professional bodies such as the European Medical Writing Association (EMWA (1)), American Medical Writing Association (AMWA (2)) and TransCelerate Biopharma Inc (3).

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Pharmaceutical physicians, scientists and clinical research professionals alike working in industry understand the importance of Good Clinical Practice (GCP) and GxP within the context of the overarching governance of clinical research and development (e.g., International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH (4)). To that end, excellence in medical writing greatly benefits all involved by promoting clear, precise documentation that supports regulatory adherence, streamlines drug approval processes, and improves clinical trial efficiencies with expert-led validated information for guidance, evaluation, interpretation and dissemination. Strong, meticulous writing skills are important to craft robust regulatory documents, such as the Clinical Study Protocol (CSP), for which high-quality input is critical to the success of the execution of the clinical trial. Principal investigators require concise, accurate, reliable and unambiguous language in protocols to avoid misinterpretation, omission or oversight, which could be severely detrimental to the research study design integrity and outcomes. For example, poorly written CSPs that contain vague, incomprehensible or imprecise information can lead to protocol deviations or amendments with consequential delays in participant recruitment, enrolment, ethics approval, clinical site administration, study duration and programme milestones, etc., not least the significant negative impact on study participants and cost implications for the sponsor.

As medically qualified pharmaceutical development specialists in industry, we aim to adopt scrutiny and high-quality standards in all our clinical development and regulatory work. Medical writing is a key part of many day-to-day routine tasks involving document drafting, reviewing, evaluation and approval. We strive to apply our expert knowledge within multidisciplinary teams to ensure rigorous ICH GCP standards are being met, while importantly ensuring participant safety is foremost in our minds when designing and developing clinical information either independently or when working collaboratively alongside colleagues, such as professional medical writers and subject matter experts.

Recently, there has been an explosion of interest in generative artificial intelligence (genAI) and AI-assisted technologies in clinical research designed to transform and improve efficiencies and proficiencies across the drug development spectrum – medical writing is no exception to this technological advancement. Automated software applications (e.g., macros, algorithms, plug-ins, etc.) have long been used in medical writing to improve editorial processes such as data transfer from source listings, proofreading, quality control (QC), referencing, and indexing to name but a few. The evolution of large language models (LLM) and genAI in this domain is a logical next step with the key rationale to help improve productivity and reduce the frequency of human error in authoring, reviewing, QC and publishing steps of the document development process. Indeed, industry is testing, exploiting and implementing AI-enabled platforms to procure and efficiently streamline regulatory documentation in various platforms, programmes and tools. In 2024, The European Medicines Agency (EMA) provided guidance (5) on the use of LLMs in regulatory science and to ensure AI technologies are used safely, ethically and effectively for medicines development. However, progress with genAI undoubtedly brings with it associated challenges and hurdles, especially in relation to precision, accuracy, and trust in scientific research integrity (6-8) inherently embedded in clinical regulatory documentation.

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As the use of genAI in medical writing evolves, this article aims to briefly provide some practical awareness and consideration of key issues relevant to the implementation of AI-assisted technologies in clinical development focused regulatory writing. Cognizance of these points may support clarification and confirmation enquiries during the document development processes and may add additional insight for comprehensive quality assurance when navigating the compilation of complex dossiers and/or critical clinical information, and for reports, files and records generated by AI-enabled technologies.

Inaccuracies and Fabrications - 'Hallucinations'

A primary concern of AI-only or AI-enabled/AI-assisted technology is AI's tendency to produce errors or invented details i.e., 'artificial hallucinations' (9, 10). These can include false data, conclusions and references, all of which may arise due to reliance of the AI programme on unverified data sources or complex data flows that cause confusion, or are due to actual technical issues with the system processing (i.e., system bug). They may all compromise the credibility of regulatory documents; for example, AI-assisted outcomes may misinterpret source data findings or create imaginary data or language that could mislead readers and harm scientific integrity. The detection of fabricated content and inaccuracies hence, demands careful expert human oversight and vigilance to catch, correct and treat such flaws (11, 12).

Embedded Algorithmic Biases and Disparities

Depending on how AI agents were trained and which agents and versions were used, AI tools can inherit and amplify prejudices from their training dataset materials, including biases (13) based on gender, ethnicity, population groups, statistics or selective data, which may distort data interpretation and skew outcomes. Consequently, this could result in the over-emphasis of certain outcomes or underrepresentation of certain groups or even data point misattribution, which may in turn lead to biased insights on demographic data, distorted efficacy and safety results or misrepresented treatment compliance among other items. Data disparities, particularly from source data listings, may be an important focus when reviewing documents, particularly if an AI-based programme drafted the version and then the same or similar AI tool QC'd the same or a different version, the analogy being the student marking their own homework, which is devoid of impartiality and is possibly delusive.

Risks to Confidentiality and Cybersecurity

Incorporating AI raises risks for confidentiality (14) and cybersecurity (15). This is especially important for sensitive data, particularly participant information and data protection, and may be more pronounced when there is a poor technical infrastructure or reliance on external platforms that may breach privacy rules. Limitations of using specialised knowledge can also affect secure data management, e.g., data may not be shared or used in the generative process due to protections or firewalls, and vulnerabilities in storage could expose confidential details to unauthorised access; this in turn could lead to data disparities and fabrications.

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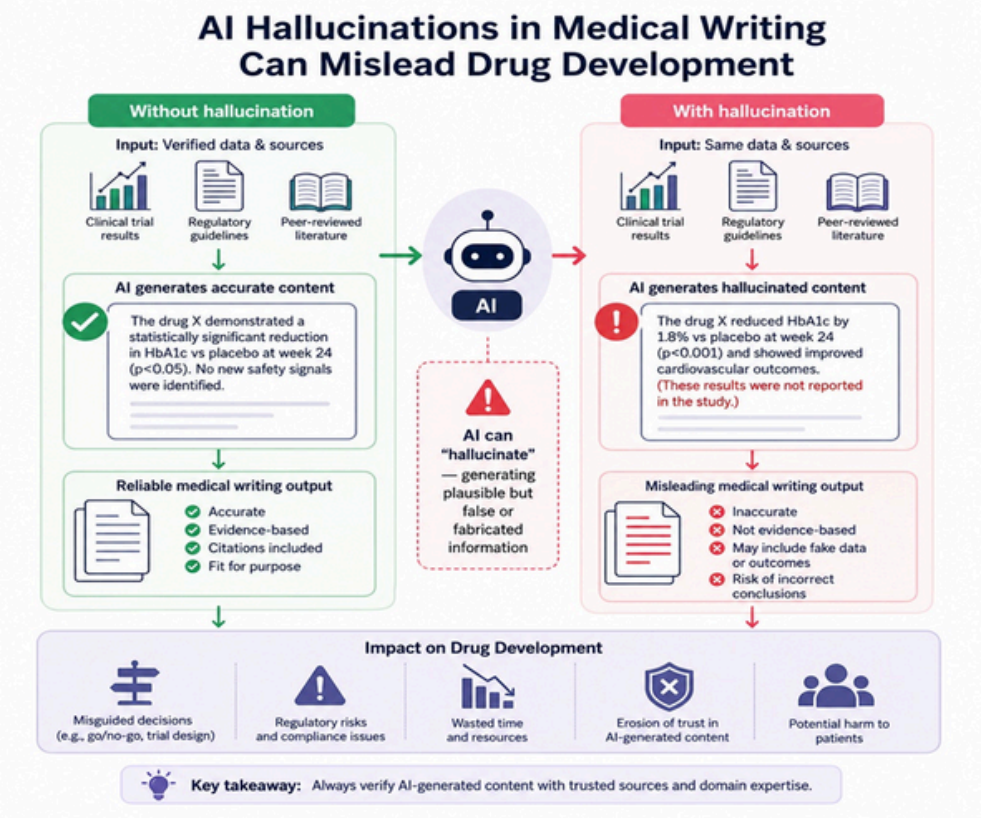
Shortcomings in Human Reasoning and Insight

AI-enabled technologies often fall short in deep clinical reasoning, analysis, logical deduction, or contextual nuance, lacking expert judgement humans provide in medical contexts (16, 17). For example, AI may struggle with adapting to changing data inputs and may be unable to accurately present primary information if there are conflicting data sources, rendering it insufficient for intricate processes when editing or reviewing, without human input. In such instances, AI automation potentially rules out semantics and syntax in the context of medical plausibility outcomes, which are only possible with inclusive human clinical expertise.



Conclusion

The integration of AI-enabled technologies in regulatory medical writing presents both promising opportunities and significant challenges. This article highlights the need for cautious adoption of AI-assisted platforms, emphasising the importance of maintaining data integrity and accuracy while being aware of key areas of concern in document development. Pharmaceutical physicians and clinical research professionals must exercise vigilance, ensuring that the information generated is reliable and credible to source. While AI platforms continue to evolve, balancing their potential benefits with the reality of current limitations is crucial. Until AI systems can consistently demonstrate validity, expert human oversight remains essential and should be maintained when used in professional practice. This stewardship is vital to uphold ethical ICH GCP standards, preserve critical review and assessment, and ensure medical plausibility, thereby mitigating risks to reliability and credibility in regulatory medical writing.

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Pharmacometrics in the Middle East and North Africa (MENA): Current Status and Regional Progress

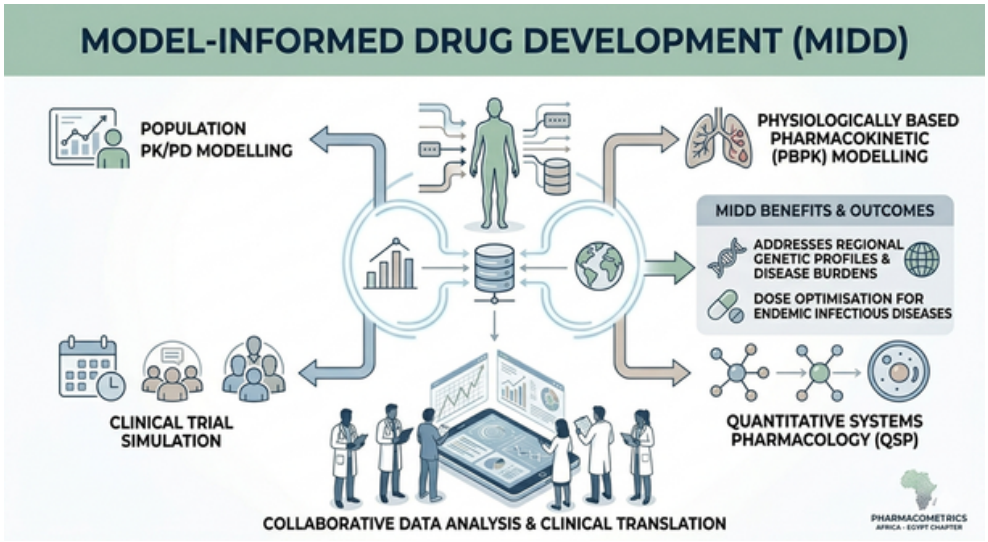
Introduction: What Is Pharmacometrics, and Why Does It Matter?

The field of drug development is becoming increasingly quantitative. Across the globe, regulators, industry scientists, and academic researchers are increasingly turning to mathematical and computational approaches to make smarter, faster, and more defensible decisions about medicines. Central to this transformation is the discipline of pharmacometrics, the science of developing and applying quantitative models that describe and predict the behaviour of drugs in the body and their effects on disease.

At its core, pharmacometrics integrates pharmacokinetics (PK) and pharmacodynamics (PD) into mechanistic or empirical models that can be fitted to data and used to simulate drug behaviour in populations that were not directly studied. The broader framework in which pharmacometrics sits (Model-Informed Drug Development, or MIDD), encompasses population PK/PD modelling, physiologically based pharmacokinetic (PBPK) modelling, quantitative systems pharmacology (QSP), disease progression modelling, and clinical trial simulation. Collectively, these approaches allow scientists to interrogate clinical questions in silico before committing to expensive and time-consuming human studies (1, 2).

The regulatory relevance of MIDD has grown substantially in recent years. The US Food and Drug Administration (FDA) launched a MIDD Pilot Programme, and the European Medicines Agency (EMA) has issued qualification opinions for model-based approaches in multiple therapeutic areas (3). Most recently, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) adopted the M15 guideline in January 2026, the first globally harmonised framework for MIDD, signalling that model-based evidence is now a core expectation of the regulatory dossier (4).

The key message is this: models are no longer supplementary to clinical data. They are increasingly the lens through which clinical data are interpreted and through which regulatory decisions are justified. Understanding pharmacometrics is becoming as essential to the pharmaceutical physician as understanding statistical methodology or clinical trial design.



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MIDD in the MENA Region: Promise Meets Urgency

The MENA region presents a compelling case for the urgent adoption of MIDD. Populations across the region carry distinct disease burdens, including high rates of infectious diseases, metabolic disorders, and non-communicable conditions, and display genetic profiles that differ meaningfully from the predominantly European and North American populations upon which most global drug development data are based. Yet, as a comprehensive 2024 review by Alasmari and colleagues noted, MENA countries remain significantly underrepresented in global pharmacometric literature and regulatory submissions (5).

When medicines are dosed and evaluated using data that do not reflect regional biology and population, the risks of suboptimal efficacy or avoidable toxicity increase. Conversely, regional data analysed through rigorous pharmacometric methods can inform dose optimisation in endemic diseases, support biosimilars and generics evaluation, and drive more rational therapeutic decision-making.

The same review emphasised the critical need for MENA countries to invest in workforce training, align regulatory frameworks with global MIDD standards, and foster collaborative research initiatives. Egypt, with its academic infrastructure and recently elevated regulatory standing, is uniquely positioned to take a leading role.

Egypt and ICH: The First African Permanent Member

In June 2023, Egypt achieved a milestone that reverberated across the African continent and the broader MENA region, following a unanimous vote at the biannual ICH General Assembly. Egypt, represented by the Egyptian Drug Authority (EDA), was confirmed as the first African permanent ICH member and the second Arab world member, after Saudi Arabia (6).

ICH membership places the EDA at the table where technical guidelines for pharmaceutical development, clinical trial methodology, and regulatory submissions are negotiated and agreed. Egypt transitions from being a guideline recipient or a country that adopts ICH standards developed elsewhere, to an active participant in shaping those standards. For MIDD specifically, this is strategically significant: the EDA has engaged with the ICH M15 working group, which developed the harmonised framework for evaluating MIDD evidence and associated regulatory practices. The guideline was adopted in January 2026, with implementation timelines running through 2026 (4).

This regulatory positioning creates both an obligation and an opportunity. To participate meaningfully in ICH technical work on MIDD, Egypt must develop and sustain a cadre of scientists, regulators, and academics who are fluent in the theory and practice of pharmacometrics. The EDA's engagement with ICH M15 is a top-down signal; the Pharmacometrics Africa Egypt Chapter represents the bottom-up response.

Pharmacometrics Africa - Egypt Chapter: Science at the Grassroots

Pharmacometrics Africa (PMX Africa) is a continental network dedicated to building pharmacometrics capacity and fostering collaborative science across Africa. In January 2026, the Egypt Chapter was formally launched, joining an established network of national chapters spanning Kenya, Nigeria, Tunisia, Uganda, and South Africa (7).

The Egypt Chapter aims to position Egypt as the regional hub for pharmacometrics and MIDD across the Middle East and Africa. Its mission rests on three pillars: capacity building through training programmes, workshops, mentorship, and fellowship support; research collaboration by connecting Egyptian researchers to the wider PMX Africa network; and knowledge exchange through seminars, webinars, and integrating pharmacometric thinking into national regulatory and academic frameworks.

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A foundational element of the Chapter's early identity is the participation of all four founding team members (Dr Aya Ismail, Dr Ibrahim Komeil, Dr Nouran Omar, and Dr Nada El Hoffy) in the 2025 PMX Africa Applied Pharmacometrics Training (APT) Fellowship (8). Through the APT programme, each member developed hands-on competence in population PK/PD modelling using platforms including Phoenix NLME, Monolix Suite, and R, and applied these skills to real-world drug development and clinical research questions ranging from antimalarial pharmacokinetics to antibody-drug conjugate modelling in oncology.

The Chapter's first structured training activity is a Clinical Pharmacology and Pharmacometrics course scheduled for July 2026. This will be sponsored by the Digital Access to Finance Holding (DAF; 9) as the initiator of the first Pharmacometrics Excellence Center in Egypt (DPEC) and delivered in a hybrid format, online and onsite, at the Faculty of Pharmacy, Future University in Egypt. The curriculum spans pharmacometric foundations, software applications, regulatory science, and case studies. In parallel, the Chapter is developing a webinar series aimed at a broader regional audience, with content spanning pharmacometrics foundations through to regulatory applications, designed to reach scientists and regulators across the MENA and African regions who cannot attend in person.

These efforts are directly aligned with the goals articulated in Egypt's Vision 2030 and the EDA's digital transformation agenda. The intersection of regulatory ambition and scientific capacity is precisely where PMX Africa's Egypt Chapter is working.

Building Capacity for a Quantitative Future

The case for investing in pharmacometrics capacity in Egypt and the MENA region is not only scientific; it is strategic. As ICH M15 moves through adoption and implementation across regulatory agencies, MIDD submissions will become an expected component of new drug applications in Egypt and the wider region. Regulators will need to evaluate these submissions critically; industry and clinical researchers will need to generate them. Neither is possible without trained people.

Critically, pharmacometrics is far more accessible than it may appear. Open-source platforms such as R and associated packages (nlmixr2, mrgsolve, rxode2), alongside other available tools within the Certara, PumasAI, and SimulationPlus ecosystems, have substantially reduced the infrastructure barrier. What is required is not an extensive laboratory but trained scientists who understand the methodology, institutions that value the approach, and networks that connect practitioners across disciplines and national borders, exactly the ecosystem that PMX Africa and its Egypt Chapter are working to build.

In this context, the Middle East Association of Pharmaceutical Medicine Professionals (MEAPP) can play a key role in advancing this agenda within the MENA region. Through its Education Working Group, MEAPP can support capacity building via targeted initiatives and regional collaborations. This includes working closely with pharmacometrics chapters, particularly in Egypt, to strengthen awareness, training, and implementation. Such efforts would help position pharmacometrics as an essential and forward-looking competency for Pharmaceutical Medicine professionals in the region.

Complementing these regional efforts, the PharmaTrain syllabus, widely regarded as a benchmark for competency-based education in Pharmaceutical Medicine, offers a valuable platform to formally embed pharmacometrics as a core component of training. Given the growing reliance

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on MIDD, exposure–response analysis, and quantitative decision-making across the drug lifecycle, the inclusion of pharmacometrics within the PharmaTrain framework is increasingly justified. It reflects not only current scientific practice but also the direction in which regulatory and industry expectations are evolving globally.

Conclusion

Egypt stands at a remarkable intersection. Its ICH membership signals a genuine intent to participate in the future of global pharmaceutical regulation. Its academic, industrial, and clinical pharmacology community, anchored in institutions like the Faculty of Pharmacy at Future University in Egypt and DAF Pharmacometrics Excellence Center, energised by the launch of the PMX Africa Egypt Chapter, is mobilising the scientific workforce that this ambition requires. The MENA region carries health challenges and genetic diversity that the global drug development system has long underserved; pharmacometrics offers a scientifically rigorous and practically feasible means of correcting this.

The momentum is real. What it now needs is sustained investment in people, continued alignment between academic, regulatory, and industry stakeholders, and the kind of international recognition and collaboration that a network like IFAPP and its national member association (MEAPP) can uniquely provide. The frontier of pharmacometrics in Egypt and the Middle East and North Africa is wide open, and the work to advance it has already begun.

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IFAPP Acknowledges Dr Otmar Kloiber's Retirement and Welcomes Dr Ramin Parsa-Parsi as WMA Secretary General

The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) would like to express its deepest appreciation on Dr Otmar Kloiber retirement from his distinguished tenure at the World Medical Association (WMA).

Throughout his decades of service, Dr Kloiber has been a steadfast guardian of medical ethics, a champion of professional integrity and an indefatigable advocate for the global medical community. His leadership has strengthened the WMA's role as a moral compass for physicians worldwide, guiding the development of ethical standards that continue to shape clinical practice, research and patient protection across all regions.

IFAPP is particularly grateful for Dr Kloiber's collaborative spirit and his unwavering commitment to constructive engagement with our organisation, which is based on our ethical framework and Memorandum of Understanding with the WMA. His openness to dialogue with IFAPP and other global partners has fostered a culture of trust, transparency and shared purpose, ensuring that ethical guidance remains relevant, inclusive and responsive to the evolving challenges of modern medicine research.

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As the world faces unprecedented transformations in science, technology, and global health, Dr Kloiber's legacy serves as a reminder of the vital importance of principled leadership. His contributions will continue to inspire all those dedicated to advancing ethical, patient-centred and socially responsible medical practice.

On behalf of IFAPP, we would like to express our profound gratitude for his exceptional service and wish him fulfilment and continued success in the next chapter of his journey.

We would also like to warmly congratulate Dr Ramin Parsa-Parsi on his appointment as the next Secretary General. Having admired his leadership in revising the Declaration of Geneva, the International Code of Medical Ethics and the Declaration of Helsinki, we are confident that these fundamental principles will underpin a successful future. We look forward to continuing to collaborate with Dr Ramin during his tenure.

With respect and warm appreciation,
on behalf of IFAPP
Varvara Baroutsou, **Chieko Kurihara**, **Kotone Matsuyama**

Otmar Kloiber MD PhD
Dr Kloiber has served as Secretary General of the WMA since 2005, after leaving the German Medical Association as Deputy Secretary General. He holds an MD and PhD from the University of Cologne, was a postdoctoral fellow in the Department of Biochemistry at the University of Minnesota, and a scientific research fellow at the Max Planck Institute for Neurological Research. Dr Kloiber holds a honorary doctorate from the Victor Babes University, Timisoara, Romania, and was appointed Clinical Professor in Health Administration (2009-2013) at the Brooks College of Health, University of North Florida. He has provided advice to numerous governments on medical ethics and socio-medical issues. His advocacy focus is on equitable access to quality healthcare for all people.

Ramin W. Parsa-Parsi MD MPH
Until his inauguration as Secretary General of the WMA effective 1 May 2026, Dr Parsa-Parsi served as the Head of the Department for International Affairs at the German Medical Association (GMA). Prior to joining the GMA, he worked with Harvard Medical International in Boston, as the Director of Health Policy. He has chaired workgroups for the aforementioned* three core ethical principles of the WMA, and holds a master's degree in public health from Harvard University, obtained a doctoral degree at the Institute of Clinical Pharmacology of the University of Heidelberg, and received his MD from the University of Cologne, where he also did his postgraduate medical education in Hematology/Oncology.

*aforementioned" means Declarations of Helsinki and Geneva, and ICoME mentioned in main text of announcement

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South African Training: Advanced Clinical Investigator (and Site Staff) Certification (CLIC) COURSE | 13 Aug - 17 Sept 2026

Clinical research practice is undergoing significant transformation following implementation of ICH E6(R3) (1), with increasing emphasis on flexible trial designs, digitalisation, data governance and risk-based quality management.

These developments require investigators and trial sites to develop new operational, ethical and quality management competencies aligned with modern clinical trial practice. Building on 10 years of clinical research training experience, Fundisa African Academy of Medicines Development (2) and Tiervlei Trial Centre (3) developed the Advanced Clinical Investigator Certification (CLIC) Course 2026 as a comprehensive hybrid programme for clinical investigators, clinical research staff, regulators, pharmacists and medical practitioners.

With the adoption of ICH E6(R3) in 2025, Good Clinical Practice (GCP) has evolved toward more flexible, principles-based support for decentralised and data-driven approaches to clinical trials. The course provides practical interpretation of these updates, with emphasis on Quality by Design (QbD), Risk-Based Quality Management (RBQM) and Critical-to-Quality (CTQ) factors.

The programme focuses on practical implementation to support regulatory compliance, participant safety, operational efficiency and data integrity. It also explores the key enablers of contemporary clinical research, including digitalisation, Artificial Intelligence (AI), operational excellence and leadership.

By integrating ICH E6(R3) and ICH E8(R1), the course provides an in-depth understanding of modern clinical trial conduct within both global and South African regulatory contexts. South African ethics committees now require professionals to be trained on NDoH 2024 (4) guidelines, as referenced in SA GCP 2020 (5).

The 2026 Advanced CLIC programme will be presented between 13 August and 16 September 2026 in a hybrid format combining face-to-face and virtual learning. The virtual option is specifically designed to provide an opportunity for international delegates to attend.

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The programme includes modules on:

- modern GCP and evolving ethics
- operational excellence at clinical trial sites
- protocol harmonisation and data reliability
- digitalisation and data governance
- AI in clinical trials
- community engagement, diversity and compliance
- leadership and risk-based quality management

Modules 1 and 2 will be offered as full-day hybrid sessions in Cape Town, while Modules 3–7 will be presented virtually as focused two-hour advanced sessions.

South African CPD accreditation has been submitted.
Programme overview: https://canva.link/qqqn32ie0df482a

References:

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2) Tiervlei Trial Centre https://ttctrials.co.za
3) Fundisa http://www.fundisa-academy.com
4) NDoH 2024: South African National Department of Health 2024 Guidelines
5) SA Good Clinical Practice Guidelines - SAHPRA

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Partnership Frontiers: Launching Research Topic

In the November/December 2025 issue of IFAPP TODAY (number 59), we announced the agreement between IFAPP and Frontiers establishing a collaborative framework aimed at enhancing the dissemination of high-quality scientific content and facilitating greater engagement within the global Pharmaceutical Medicine community. Through this partnership, IFAPP will work closely with Frontiers in Pharmacology, a leading open-access journal, to promote research, foster dialogue, and support innovation in the development and regulation of medicines.

Here is the link to the agreement (Agreement) and the IFAPP Point of Contact (PoC) for this initiative is Robert Lins, Chair of the External Affairs Working Group (EAWG), Email: robert@linsconsulting.be

As a key part of this agreement, the first organisation research topic for the collection of articles proposed by IFAPP, has been launched by Frontiers in Pharmacology on their website (link: Future of Pharmaceutical Medicine).

The title of the topic is The Future of Pharmaceutical Medicine, with the subtitle Medicines R&D Ethics, Regulation and Governance in a Transforming AI Ecosystem for EU.

Topic editors are Varvara (Barbara) Baroutsou, Immediate Past President, Haya Haddadin, EAWG Member, and Robert Lins, EAWG Chair.

This research topic focuses on three interconnected themes:

1. Professionalisation and Education in Pharmaceutical Medicine
2. Specialist recognition and harmonisation of training across jurisdictions
3. Workforce transformation as a major bottleneck.

You can find more details about the topic here: Future of Pharmaceutical Medicine

We cordially invite you to contribute as authors. In particular, we encourage submissions from speakers and participants of our International Conference of Pharmaceutical Medicine (ICPM) held in Amsterdam in April 2025. The manuscript submission deadline is 28 February 2027.

Please feel free to contact me for further information or to indicate your intention to submit. IFAPP members (whether through a national member association or as individual affiliates) are eligible for a 15% discount on article processing charges for accepted manuscripts, which will be reimbursed by IFAPP.

Author:
Robert Lins, MD, PhD, Specialist in Clinical Pharmacology and Pharmaceutical Medicine, Chair of the IFAPP External Affairs Working Group (EAWG)

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IFAPP's Continuing Discussion on Data-Driven Research, Collaboration between Ji4pe, EUPATI and Japanese NMA JAPhMed

Creating Values with the Concept of "Process Economy"

IFAPP continues to provide a discussion forum for the ongoing revision of the World Medical Association (WMA)'s Declaration of Taipei (DoT) (1) on health databases and biobanks, motivated by global interests in data-driven research. At the IFAPP Webinar of 23 March 2026, the Bioethics Working Group (WG) of the Japanese Institute for Public Engagement (Ji4pe) expressed their opinions (2) on the Declaration of Taipei. The results were reported in the previous issue of IFAPP TODAY, No. 63, together with the current status of the WMA's revision at their open meetings (3). Subsequently, the Bioethics WG of Ji4pe received feedback from the European Patients' Academy on Therapeutic Innovation (EUPATI), an organisation promoting patient engagement in medicines development in Europe, during a closed session on 6 April 2026. Furthermore, on 8 April 2026, the Ji4pe Bioethics WG and leaders of IFAPP's National Member Association (NMA) in Japan, the Japanese Association of Pharmaceutical Medicine (JAPhMed), discussed the details of a patient registry project.

These discussions will be linked to the JAPhMed-IFAPP collaborative session on 25 July 2026 at the JAPhMed Annual Meeting, where Japanese experts of Pharmaceutical Medicine and the patient group will discuss the ethics of data-driven research. Dr Eric Klaver, current President of IFAPP, will give a video message, and Professor Kotone Matsuyama, President-elect of IFAPP, will make a presentation.

This series of sessions embodies the concept of "process economy", proposed by Dr Shinichi Nishiuma, President of the JAPhMed Annual Meeting 2026 (and member of the IFAPP Education and Communication Working Group). In essence, "process economy" is a concept whereby value is generated through a continuous process of exchanging views between the global community of IFAPP, Japanese groups of experts, patients, and a European patient group. This report outlines the outcomes of this series of sessions.

Ji4pe Bioethics WG and EUPATI Session (6 April 2026):
Feedback from EUPATI on the views of the Japanese patient group on the DoT

This session was held as Part 2 of the "Global Dialogues among Patients and the Public on Research Ethics". Part 1 was featured in IFAPP TODAY No. 62 (4).

Ms Sabrina Grigolo and Ms Jana Popova from EUPATI have been participating continuously in the ongoing discussions. EUPATI expressed its support for the Japanese patient group, noting that there is great significance in patient and public participation in discussions regarding health databases and biobanks. The Japanese patient group asked about the activities in Europe to promote the engagement of vulnerable patients, especially in light of the rapid development and use of artificial intelligence (AI). EUPATI replied that it had already produced educational materials on data-driven research and that the WMA's DoT on health databases and biobanks would likely serve as a useful awareness-raising resource in the future. It was also noted that materials had already been produced to facilitate the participation of underserved and underrepresented patient groups in clinical research.

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Table 1 summarises the materials introduced during the session regarding (i) general patient engagement, as well as those concerning (ii) data-driven research and (iii) underrepresented groups. It was also mentioned that, as the European Union is currently developing regulatory frameworks such as the General Data Protection Regulation and the European Health Data Space, initiatives to improve the health literacy of the general public are also being advanced.

Table 1 EUPATI's material for patient engagement in general, for real-world evidence generation and for underrepresented populations

(i) Patient Expert Training Programme https://learning.eupati.eu/admin/tool/custompage/view.php?id=3 The EUPATI Patient Expert Training Programme covers the entire lifecycle of medicines research and development (R&D) (see roadmap here), from design and execution of research projects and clinical trials to regulatory processes and Health Technology Assessment (HTA). In addition to detailed information on each step of the process, the training also describes how patients can be involved in each stage. Graduates of the EUPATI Patient Expert Programme are known as **EUPATI Fellows** or **Alumni.**
(ii) Guidance for Patient Engagement in Real World Evidence Generation https://eupati.eu/projects/greg/ The GREG project ("Testing, improving, and co-creating Guidance and Tools for Real World Evidence Generation and Use for Decision-making in Europe") is a five-year European initiative that started in May 2025. It is funded by the Innovative Health Initiative (IHI; https://www.ihi.europa.eu) and brings together experts from universities, industry, regulators, patient groups, and other organisations.
(iii) Project for Engagement of Underrepresented Populations https://eupati.eu/readi/ In January 2025, the pioneering project READI – Research in Europe and Diversity Inclusion – was launched in Madrid. This is a Horizon Europe Innovative Health Initiative (IHI) project (https://ihi-readi.org) with the goal of promoting a less fragmented and more democratic ecosystem for clinical studies. Underserved and underrepresented populations in Europe, including ethnic minorities, older people, and socioeconomically disadvantaged groups, are often excluded from clinical studies. This creates gaps in understanding diseases and limits access to innovative health technologies.

Table reproduced from the aforementioned EUPATI's website with small edits

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Ji4pe Bioethics WG and JAPhMed Session (8 April 2026):
Dialogue between experts and patient representatives using a patient registry project as a case study

Three leaders from JAPhMed discussed the project with the Ji4pe Bioethics WG. They were Dr Shinichi Nishiuma (Chair of the 2026 JAPhMed Annual Meeting), and Dr Atsushi Kuga (Chair of the JAPhMed Clinical Development Committee), who had both delivered the opening remarks at the IFAPP Webinar of 23 March 2026, and Professor Hideki Oi (former Chair of the JAPhMed Clinical Development Committee).

Professor Oi gave a detailed explanation of the patient registry project for mental disorders (Figure 1), whilst the Ji4pe Bioethics WG presented their views on the Declaration of Taipei, followed by a discussion. Professor Oi explained that initiatives to enhance data security and reliability for the use of real-world data in regulatory decision-making have been incorporated based on consultations with regulatory authorities. The patient and public group expressed interest in the project's sustainability and the potential for expansion to cover a wider range of target diseases. Professor Oi explained that the continuation of publicly funded projects requires demonstrating outcomes at each stage, with a future expectation of self-sustaining operations. Regarding the expansion of patient groups and target diseases, he noted that this is currently being pursued primarily through collaborative research with various institutions. JAPhMed experts expressed surprise at the depth of understanding demonstrated by the trained patient group.

The patient group's views on the Declaration of Taipei call for high ethical standards, including equitable benefit-sharing, the prohibition of exploitation, initiatives towards the Sustainable Development Goals (SDGs), and strict security and governance. However, as these represent advanced principles rather than merely procedural requirements, they resonated with the JAPhMed experts, raising expectations for future collaboration. In particular, whilst projects concerning the diagnosis of diseases caused by single-gene mutations have been progressing domestically in recent years, expectations are growing for global research and development into rare genetic diseases affecting only one to a few people within a country. At the same time, genomic information is recognised as a critical issue in national security. Cybersecurity and data governance are key challenges.

JAPhMed experts noted that, in order to provide feedback on research results to patients participating in registry studies, various methods should be considered - such as obtaining dynamic consent from individual participants (using an electronic device to secure ongoing consent each time a new secondary use study begins, as shown in Figure 1), disseminating information via the research project's website, and organising academic society events for public awareness, as well as publishing newsletters. They emphasised that there is no single solution, and that it is necessary to employ a variety of methods to raise awareness depending on the situation.
It is anticipated that this discussion will be further explored during a session on 25 July 2026, in collaboration with IFAPP at the JAPhMed Annual Meeting. See the detailed information via the link (Japanese only) https://japhmed.jp/japhmed2026/.

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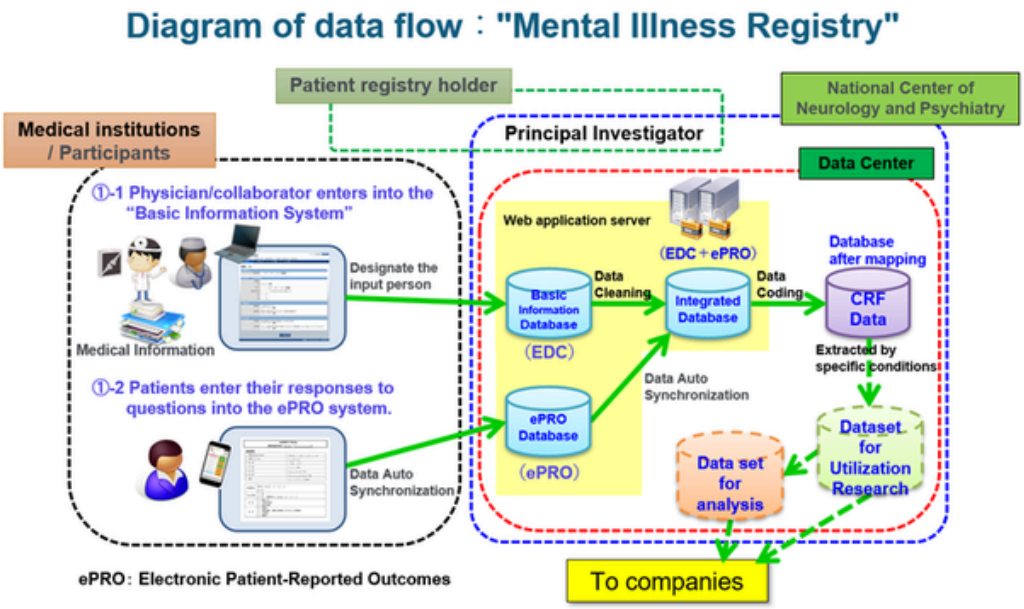
Figure 1 Diagram of data flow to show that "dynamic consent" is technically possible, explained by Professor Oi, JAPhMed, to a Japanese patient group



This diagram of the data flow in "Mental Illness Registry" developed at the National Center of Neurology and Psychiatry, was presented by Professor Oi. In this project, patients will enter their responses to questionnaires into an electronic patient-reported outcomes (ePRO) system. For this reason, it is possible to contact the registered patients through the electronic devices they use. This means that "dynamic consent" is technically possible.

JAPhMed leaders contributing sessions:
Shinichi Nishiuma, MD (left) President of 2026 Annual meeting, Founder and CEO, Nishiuma Co., Ltd.
Atsushi Kuga, MD, PhD (middle), Head of Clinical Development Committee, JAPhMed;
Hideki Oi (right), Professor, Kyorin University School of Medicine

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(1) The World Medical Association. The Declaration of Taipei on ethical considerations regarding Health Databases and Biobanks. 2002, last revised 2016.

(2) Kurihara C, Saito Y, Inoue K, Kai H, Kishi N, Kuge A, Murakami T, Takahashi H, Uchida E, Wakasa K, Imamura K. Opinions from patients and the public for the revision of the WMA Declaration of Taipei. Clinical Evaluation. 2026; 54(1).

(3) Kurihara C. A Series of Discussions on the Revision of the WMA Declaration of Taipei on Health Databases and Biobanks: Facilitate Expanded Participation of Patients and the Global South. IFAPP TODAY. 2026; April (63): 18-23.

(4) Grigolo S, Popova J, Kurihara C. Global Dialogues among Patients and the Public on Research Ethics Part 1: EUPATI's view on the GREEN Statement for a Japanese group of patients and the public (Ji4pe Bioethics Working Group). IFAPP TODAY. 2026; March (62): 13-16.

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Summary of the IFAPP Webinar of 15 April 2026

New Provisions in the Pharmaceutical Legislation
Will They Solve the Future Challenges Concerning Pharmaceuticals?

Speaker:
Prof. Dipl. Ing. Dr Christa Wirthumer-Hoche,
Graduated in biochemistry at the Technical University, Vienna, Austria,
From 2013 – 2023 appointed Head of the Austrian Agency for Medicines and Medical Devices.
Currently Consultant to the Austrian Ministry of Health during the review of the general Pharma legislation

Dr Wirthumer-Hoche started her presentation with the description of the challenges ahead:

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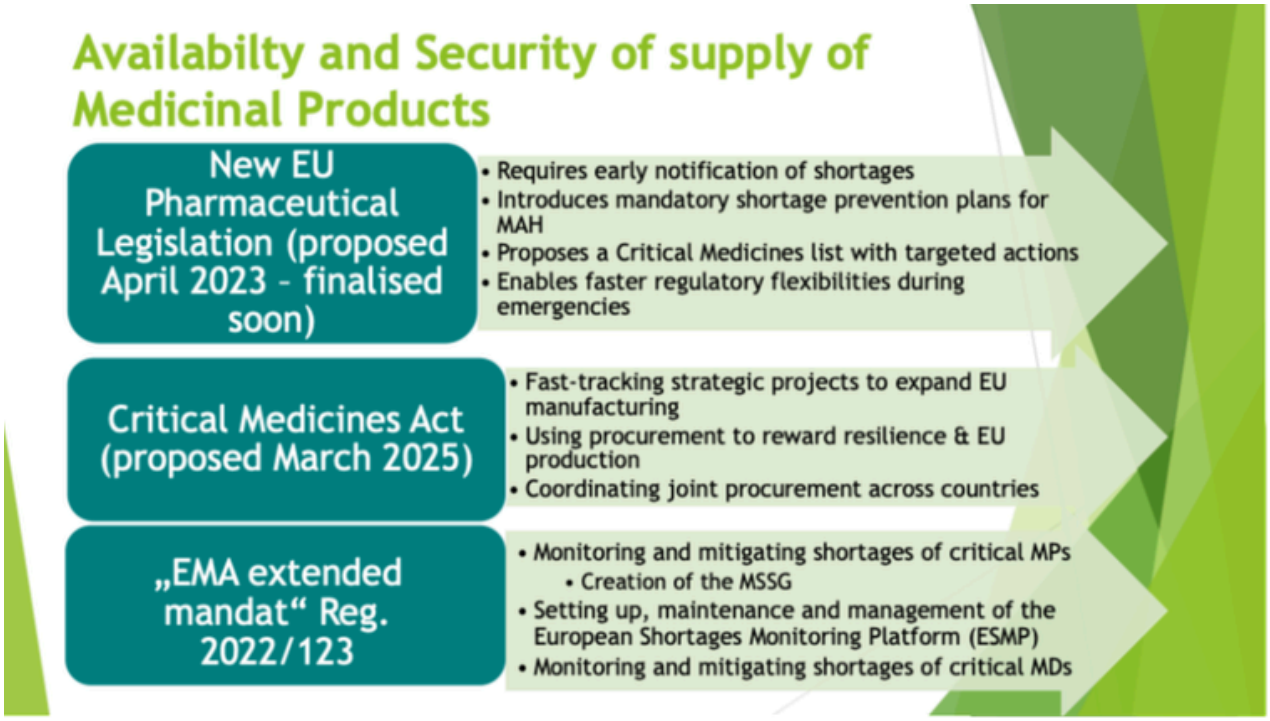
Dr Wirthumer-Hoche also pointed out which of the topics have to be solved or at least touched upon in the Revision of the EU Pharma Legislation which means in the Regulation and the Directive.

She also provided information regarding the matrix structure of different legal acts in relation to availability and security of supply of Medicinal Products:



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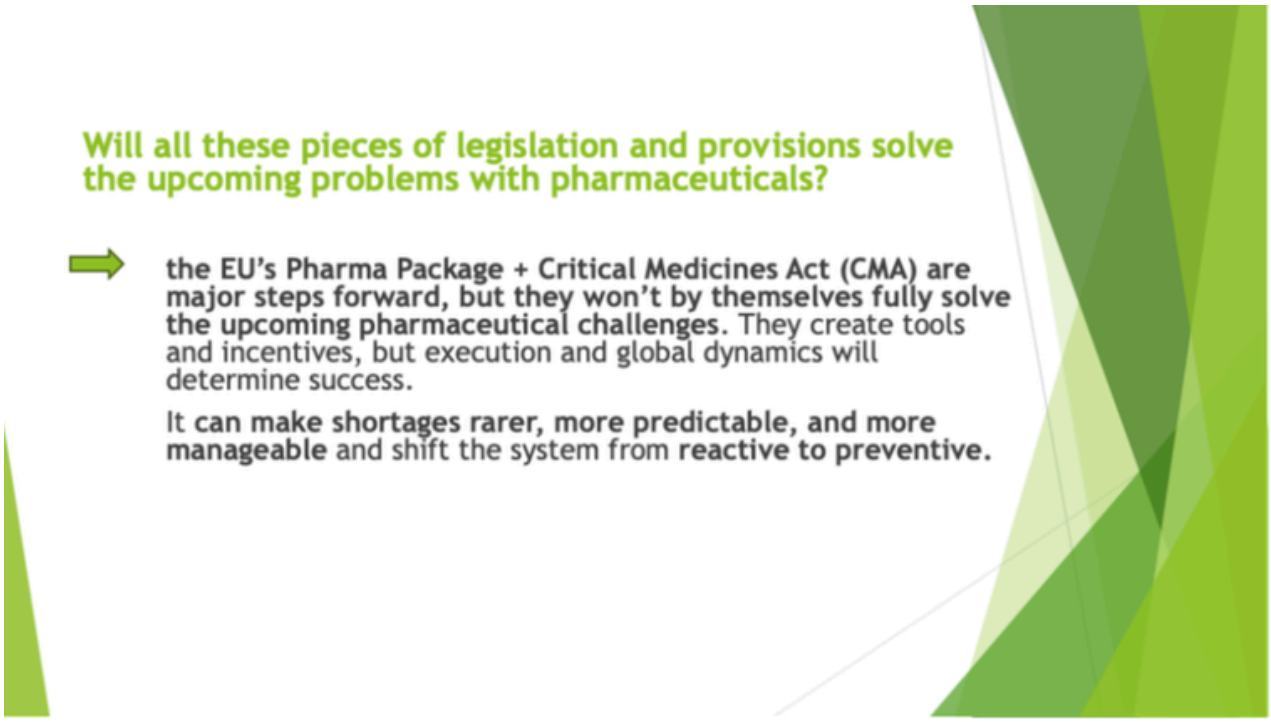
And last but not least Dr Wirthumer-Hoche reflected on the importance of the European Health Data Space Regulation and in this the new challenges of Artificial Intelligence:

She concluded:



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The recording of the presentation is here https://youtu.be/IJdX6VtDUXY

Authors:
Birka Lehmann, MD PhD, Chair of IFAPP's Education and Certification Working Group (ECWG),
Prof. Dipl. Ing. Dr Christa Wirthumer-Hoche

Free Webinar: Part 4: Perspectives of Global South, Resource-limited regions, Indigenous people and Vulnerable Patients - 25 May 2026, 13:00 CEST

Date and Time Frame:
25 May 2026, Monday 3 hours:
13:00 - CEST, SA
14:00 - Greece
20:00 - JST
19:00 - Philippine
08:00 - Brazil, Argentina
07:00 - EDT

Free registration via the link or QR Code below.

Part of the leaflet: Click here for more details including titles of presentations.

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Free Webinar: "Are We Running out of Antimicrobials?" - 26 May 2026, 12:00 noon CES

The following webinar on «Are we running out of antimicrobials?" to be given by Professor Silvio Brugger from the University in Zurich, Switzerland, on 26 May, 12.00 noon CEST, will provide information on why the development of new antibiotics is of tremendous importance on a national and also on a global level!

This is also addressed in the new EU pharma legislation as pointed out by Professor Christa Wirthumer-Hoche in the webinar of 15 April 2026:

"The new pharma legislation aims to address antimicrobial resistance by introduction of transferable exclusivity vouchers to encourage development of priority antibiotics, with safeguards to protect national healthcare budgets!"

Antimicrobial resistance (AMR) is increasingly challenging modern medicine and raising a pressing question: are we approaching a post-antibiotic era? This webinar examines the current situation in Switzerland and internationally, focusing on what happens when no effective antibiotic is available for a patient. We will explore how often such situations occur, which pathogens are most concerning, and which patient populations are particularly at risk (especially critically ill patients in intensive care units; ICUs), as well as vulnerable groups in more general clinical settings. The discussion will address multidrug-resistant organisms, treatment limitations, clinical outcomes, and the real-world consequences for patient safety, hospital workflows, and healthcare systems.

Speaker: Professor Dr Silvio Daniel Brugger, FESCMID

Prof Silvio Brugger is a Senior Attending Physician and Head of the Clinical Microbiology Laboratory (Hospital Epidemiology Laboratory) in the Department of Infectious Diseases and Hospital Epidemiology at the University Hospital Zurich, Switzerland. He is also a Professor at the University of Zurich holding an SNSF (1) Starting Grant. He teaches at the ETH (2) and the University of Zurich.

As a Fellow of the European Society of Clinical Microbiology and Infectious Diseases (FESCMID), Professor Brugger serves on ESCMID's Executive Committee and the Swiss Society for Infectious Diseases as well as the ESCMID guideline committee. He holds Swiss Board Certifications in Internal Medicine and Infectious Diseases, with a focus on AMR, microbiota and bacterial colonisation.

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After completing Switzerland's national MD-PhD programme, Professor Brugger pursued postdoctoral research at Harvard Medical School in Cambridge, USA. His work has earned multiple awards, including the Siegenthaler (3) and SGM (4) Awards, and he completed his habilitation at the University of Zurich in 2021. Professor Brugger's research emphasises microbiota-targeted strategies to combat AMR and his clinical expertise focuses on multidrug-resistant (MDR) infections.

Abbreviations:
(1) SNSF: Swiss National Science Foundation
(2) ETH: Eidgenoessische Technische Hochschule (Federal Institute of Technology) Zurich
(3) Siegenthaler award is a prestigious award given by the Walter and Gertrud Siegenthaler Foundation to outstanding young researchers in the field of medicine
(4) SGM: Swiss Society for Microbiology

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Free Webinar: "Level Up Your Career: The Mentorship Advantage" - 19 June 2026, 12:00 noon CET

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Upcoming Free Webinars

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  Click here to register.
- 26 May 2026 - Are We Running out of Antimicrobials?
  Click here to register.
- 19 June 2026 - Level Up Your Career: The Mentorship Advantage
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