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INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

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MED-e-Vigilance: A New Dimension of MEDDEV Vigilance

Abstract
Cybersecurity failures in digitally enabled healthcare are generating a new category of clinically relevant adverse events. Electronic health records, cloud-linked diagnostic systems, laboratory information systems, networked therapeutic devices, and implantable medical devices are now embedded within routine care. Conventional pharmacovigilance and medical device vigilance systems are designed to identify, assess, report, and prevent harms from medicines and devices, but they are not optimally structured to capture cyber-initiated patient harm or healthcare disruption. This article proposes MED-e-vigilance as an extension of medical device vigilance and patient-safety surveillance. MED-e-vigilance refers to the systematic identification, assessment, reporting, mitigation, and prevention of patient harm or healthcare disruption arising from cybersecurity failures affecting medical devices, digital clinical infrastructure, or interconnected healthcare information systems. Recent incidents including WannaCry, the Ireland Health Service Executive attack, Change Healthcare, and Synnovis, demonstrate that cyber events can delay diagnosis, interrupt treatment, disrupt diagnostic and pharmacy services, and weaken healthcare continuity. The article outlines a device–service–system framework for cyber-clinical incidents, highlights regulatory gaps, and proposes integration of cyber incidents into routine vigilance and patient-safety governance.

Keywords: cyber incident; medical device vigilance; MEDDEV vigilance; digital health; ransomware; implantable medical devices; patient safety; cybersecurity

Introduction

Digitally enabled healthcare delivery is expanding rapidly. Electronic health records, telehealth platforms, cloud-connected diagnostic systems, software as a medical device, and implantable medical devices are now part of an interconnected clinical ecosystem. While this connectivity improves diagnosis, monitoring, and continuity of care, it also creates a new category of risk: cyber-initiated clinical incidents.

Conventional pharmacovigilance and medical device vigilance systems are structured around the detection, assessment, reporting, and prevention of adverse events associated with medicines and devices. MEDDEV vigilance and its successor frameworks under the EU Medical Device Regulation (MDR) emphasise serious incident reporting, field safety corrective actions, trend analysis, and post-market surveillance. However, these systems were not originally designed for healthcare environments in which ransomware attacks, compromised clinical data pathways, or vulnerabilities in connected devices can disrupt care at scale (1, 2).

This article proposes MED-e-vigilance as an expanded vigilance concept for the digital healthcare era. MED-e-vigilance may be defined as:

The systematic identification, assessment, reporting, mitigation, and prevention of patient harm or healthcare disruption arising from cybersecurity failures affecting medical devices, digital clinical infrastructure, or interconnected healthcare information systems

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The concept extends beyond device hacking alone and includes device compromise, data-path disruption, service denial, and system-level digital failures that create clinical risk. The central argument is not merely that medical devices can be hacked, but that cyber incidents should be incorporated into structured patient-safety and vigilance systems with defined reporting pathways, clinical outcome assessment, and resilience measures comparable to those used in pharmacovigilance and medical device vigilance.

From MEDDEV vigilance to MED-e-vigilance

MEDDEV vigilance traditionally focuses on identifying, reporting, and correcting incidents related to medical device safety and performance in real-world use. Under the EU MDR and In Vitro Diagnostic Regulation (IVDR) post-market surveillance and vigilance requirements have expanded to include software-containing devices, risk management, and information security considerations.

However, cyber-clinical harm does not always fit precisely into conventional vigilance categories. A ransomware attack affecting a pathology provider may delay cancer diagnosis or transfusion services without involving a physically defective device. Similarly, disruption of prescribing systems or clinical data pathways may alter patient management without direct hardware malfunction.

MED-e-vigilance therefore extends existing vigilance logic into the digital healthcare ecosystem. It does not replace cybersecurity governance or hospital Information Technology (IT) management; rather, it connects cyber incidents with patient-safety surveillance and clinical governance.

A useful distinction is depicted in the following table.

Domain	Primary focus
Pharmacovigilance	Harm from medicines
Medical device vigilance	Harm from device malfunction or performance failure
Cybersecurity governance	Protection of systems, software, and networks
MED-e-vigilance	Clinical harm or healthcare disruption arising from cyber-related digital failure

This framing positions MED-e-vigilance as a clinical safety layer rather than a purely technical cybersecurity concept.

Why recent cyber incidents matter

Several recent incidents demonstrate the clinical consequences of cyber failures. The 2017 WannaCry attack disrupted National Health Service (NHS) and delayed care across UK hospitals (3). The 2021 Ireland Health Service Executive ransomware attack forced national healthcare services into manual workflows and interrupted continuity of care (4). In 2024, the Change Healthcare attack disrupted prescribing, pharmacy, and payment systems across the United States (5), while the 2024 Synnovis ransomware attack cascaded from pathology systems across southeast London into primary care, with >10,000 outpatient appointments and 1,710 elective procedures cancelled and week-long disruption to general practice workflows; and the recovery took almost 16 weeks (6). Together, these events demonstrate that cyber incidents can impair diagnosis, therapeutics, monitoring, and healthcare continuity at device, service, and system levels.

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Cyber-clinical incidents may occur at three interconnected levels as depicted in Figure 1:

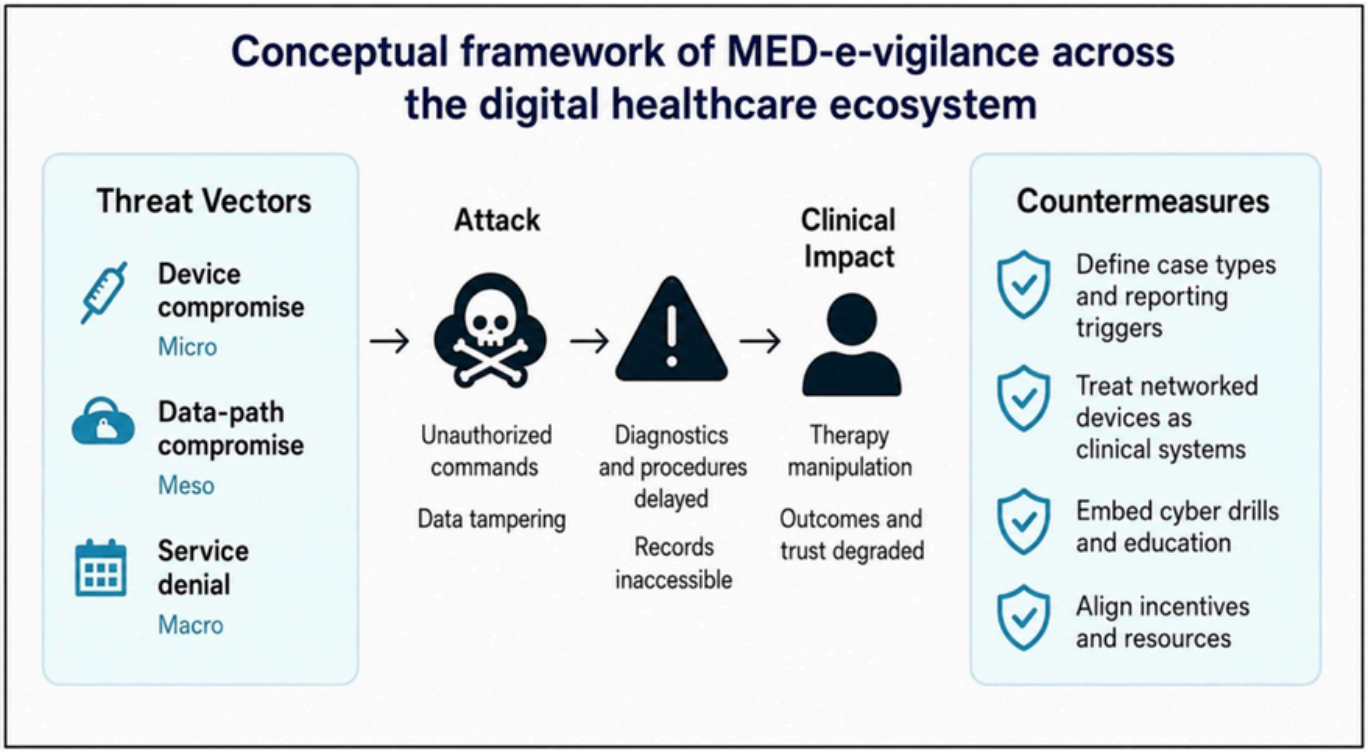

Figure 1: Conceptual framework of MED-e-vigilance across the digital healthcare ecosystem. *The left panel classifies threat vectors by care layer: micro (device compromise of implantable and connected tools), meso (data-path compromise across labs/Electronic Health Record (EHR)/scheduling), and macro (service denial affecting networks and infrastructure). The central pathway depicts attack progression and consequences: unauthorised commands and data tampering → delayed diagnostics/procedures and inaccessible records → clinical impact including therapy manipulation, worsened outcomes, and loss of trust. The right panel outlines countermeasures: define case types and reporting triggers; treat networked devices as clinical systems; embed cyber drills and clinician education; and align incentives/resources to strengthen resilience.*

Clinical consequences may include delayed diagnosis, interrupted therapy, cancelled procedures, device malfunction, adverse drug events, and loss of trust. This framework shifts the discussion from "Was a device hacked?" to "Did digital failure create clinical risk?"

Regulatory evolution and remaining gaps

Regulators increasingly recognise cybersecurity as part of medical device safety. The EU MDR requires software-containing devices to incorporate risk management, information security, verification, and validation principles throughout the lifecycle. FDA cybersecurity guidance similarly emphasises secure-by-design development, threat modeling, vulnerability management, and lifecycle cybersecurity oversight. The Global Harmonisation Task Force / International Medical Device Regulators Forum (GHTF/IMDRF) guidance also provides a framework for adverse-event reporting, follow-up investigation, and trend analysis relevant to cyber-related incidents (7-10).

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Despite these advances, important gaps remain. Cyber incidents affecting laboratories, prescribing systems, cloud services, or hospital networks may fall outside conventional device reporting structures despite producing patient harm. In addition, cyber events often involve multiple stakeholders, including manufacturers, hospitals, cloud providers, laboratories, and national infrastructure systems, making accountability complex. Clinical consequences such as delayed diagnosis, interrupted therapy, or downstream morbidity are also poorly captured in existing reporting systems.
MED-e-vigilance addresses these gaps by translating cyber incidents into structured patient-safety and clinical governance language.

Implantable devices: fact, fiction, and proportionate vigilance
Debate surrounding implantable medical devices is often polarised between two extremes: that connected implants are dangerously hackable, or that cybersecurity risks are largely theoretical (11). A more appropriate approach is risk-balanced realism.

Wireless and networked implantable devices, including cardiac implantable electronic devices, insulin pumps, and neurostimulators, carry credible cybersecurity risks because they depend on telemetry, Bluetooth, cloud systems, and hospital networks. These pathways may theoretically permit unauthorised access, spoofing, therapy interference, or data manipulation.

However, the observed real-world risk of malicious patient harm remains low compared with the established benefits of remote monitoring and connected care. Remote monitoring of cardiac implantable devices, for example, can improve follow-up, reduce hospitalisation, and support earlier clinical intervention (12).

MED-e-vigilance should therefore avoid alarmism. The goal is not to reject connectivity, but to ensure adequate safeguards, reporting mechanisms, clinician education, and regulatory oversight to identify and mitigate cyber-related clinical risk. For implantable devices, this includes secure-by-design development, strong authentication, secure software updates, vulnerability disclosure pathways, and post-market surveillance of cyber-related performance issues.

From cybersecurity management to clinical vigilance
The novelty of MED-e-vigilance lies in converting cybersecurity incidents into clinically reportable patient-safety events. Traditional cybersecurity responses focus on compromised systems, exploited vulnerabilities, data loss, and operational recovery. MED-e-vigilance asks additional clinical questions:

- Was diagnosis delayed?
- Was treatment interrupted?
- Were medicines inaccessible?
- Did device malfunction create patient risk?
- Did workaround processes introduce clinical errors?
- What patient outcomes occurred?
- What should be reported, and through which vigilance pathway?

This approach transforms cyber response from purely technical recovery into patient-safety learning and resilience improvement.

Practical implementation
Healthcare systems should define reportable cyber-clinical events and integrate them into existing vigilance and governance structures. Suggested categories include:

- device-centric compromise (already in place)
- data-path compromise (partly by IT support)
- service-denial harm
- system-level digital cascade

Connected medical devices should be treated as clinical systems rather than isolated hardware, with cybersecurity integrated into pre-market evaluation, post-market surveillance, and resilience planning.

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Clinicians should also receive practical training through cyber-clinical simulation exercises involving EHR downtime, device telemetry failure, prescribing disruption, laboratory outages, or ransomware-related care interruption to master "biotechnological syndromes"—clinical presentations where digital tech is part of the pathology (13). Major cyber incidents should be incorporated into morbidity and mortality review, clinical governance, and patient-safety reporting processes.

A practical MED-e-vigilance workflow is summarised in Figure 2 and includes recognition, risk stratification, stabilisation, reporting, and post-incident learning. The framework translates cyber incidents into clinically actionable patient-safety events integrated within routine governance and vigilance systems.

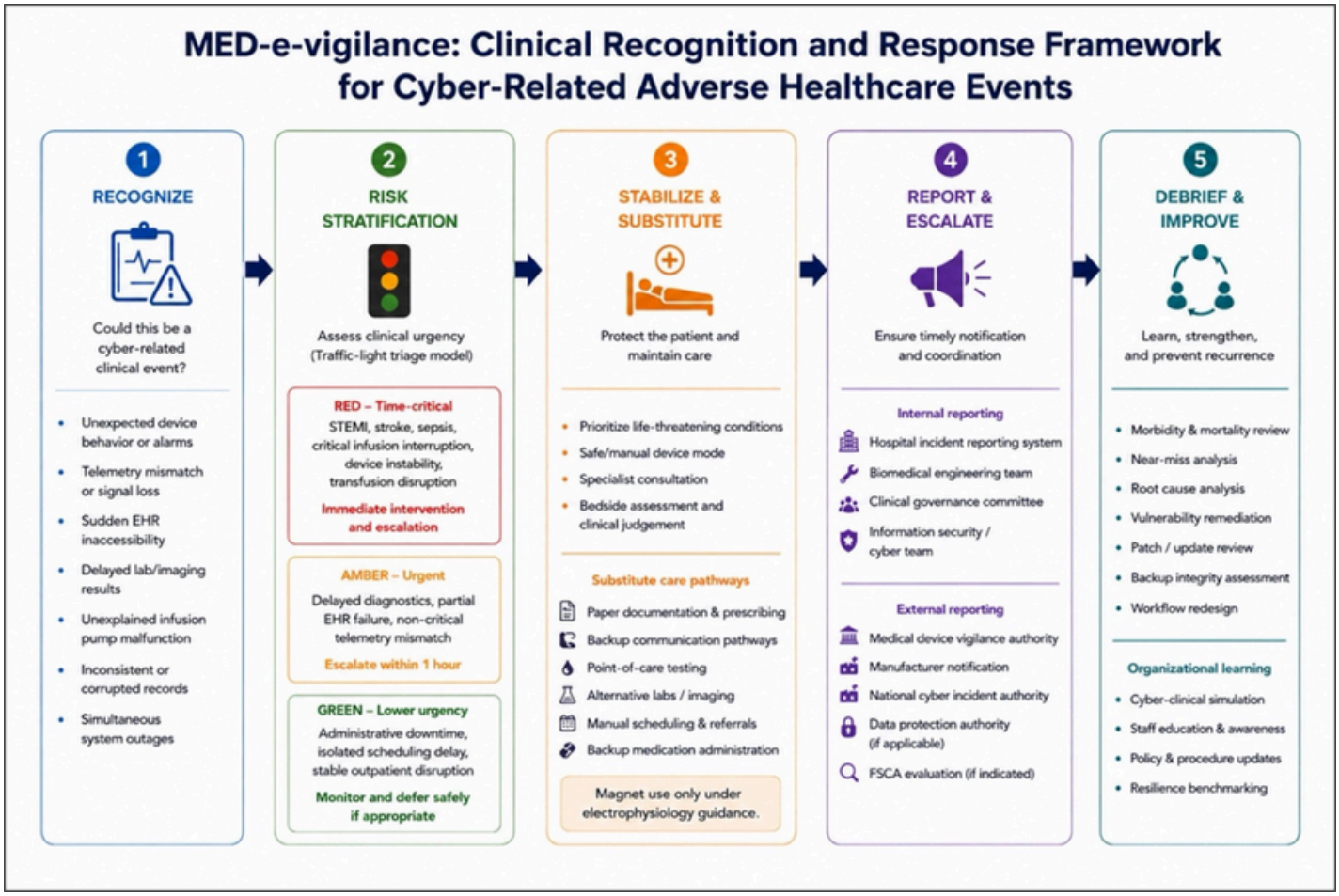

Figure 2: MED-e-vigilance: Clinical recognition and response framework for cyber-related adverse healthcareevents.

The figure illustrates a proposed MED-e-vigilance workflow that translates cybersecurity incidents into clinically actionable patient-safety events. The framework outlines five sequential stages: 1) recognition of potential cyber-related clinical disruption affecting devices, records, diagnostics, or healthcare services; 2) risk stratification using a traffic-light triage model based on clinical urgency rather than technical severity alone; 3) stabilisation of the patient and substitution of disrupted care pathways using contingency workflows and device-specific precautions; 4) structured reporting and escalation through internal governance systems and external vigilance,

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cybersecurity, manufacturer, and regulatory channels; and 5) post-incident debriefing, systems review, and organisational learning to strengthen healthcare resilience and reduce recurrence. The framework integrates device compromise, service disruption, and system-level digital failures into routine clinical governance, patient-safety surveillance, and MED-e-vigilance practice.

Conclusion

Like pharmacovigilance and medical device vigilance, MED-e-vigilance aims to identify, assess, report, prevent, and minimise harm. The difference is that the hazardous agent may not be a molecule or mechanical defect, but malicious code, software vulnerability, corrupted data, or unavailable digital infrastructure.

Healthcare has entered an era in which cybersecurity failure can become clinical failure. MED-e-vigilance provides a practical conceptual bridge between cybersecurity, medical device regulation, and patient-safety surveillance. Its purpose is not to create another administrative label, but to ensure that cyber incidents are evaluated according to what matters most: their impact on patients, clinical care, and healthcare resilience.

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Tackling Antibiotic Resistance through European Cooperation: The role of the European Partnership One Health Antimicrobial Resistance (OHAMR)

Introduction

Antimicrobial resistance (AMR) is currently one of the greatest challenges to global public health in the 21st century. The increasing ineffectiveness of antibiotics not only threatens the treatment of infectious diseases but also calls into question key medical procedures such as surgical interventions, organ transplants and cancer therapies. Against this backdrop, the promotion and implementation of intensive international cooperation in research and innovation is becoming increasingly important.

The scale of the challenge

The World Health Organization (WHO) classifies AMR as one of the ten greatest threats to global health. At the European level, too, AMR is regarded as a truly critical risk: the European Commission's Health Emergency Preparedness and Response Authority (HERA) currently lists it among the three high-priority health threats.

Current modelling predicts a drastic increase in the global burden of disease over the coming decades. Estimates suggest up to 39 million deaths by 2053 as a result of resistant infections, should no effective countermeasures be taken.

The causes of this trend are manifold:

- Inappropriate and excessive use of antimicrobial substances (and resulting supply shortages),
- Stagnating development of new antibiotics,
- Global disparities in access to healthcare, water and sanitation,
- Environmental pollution, particularly from pharmaceutical production waste.

Unfortunately, these factors also extend beyond the human health sector and affect animal husbandry, agriculture and the environment as well. This highlights the need for an integrated **One Health approach** that encompasses all relevant sectors.

A significant step in this direction was the establishment of the European Partnership on One Health Antimicrobial Resistance (EUP OHAMR) in 2025. The first annual meeting, held in March 2026 at the Austrian Agency for Health and Food Safety (AGES) in Vienna, marks an important milestone in the strategic development of this partnership.

EUP OHAMR: Structure and objectives

The EUP OHAMR was established to pool and coordinate Europe-wide and international research and innovation activities to combat AMR. The partnership currently comprises 53 **organisations from 30 countries**, which work closely with the European Commission.

The programme is designed to run for **ten years (2025–2035)** and has a total budget of around **250 million euros** for research and innovation projects. In addition, the European Union is providing up to **75 million Euros** in co-funding. The coordination is handled by the **Swedish Research Council (SRC).**

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The EU partnership pursues several key objectives:

- Promoting interdisciplinary research based on the One Health principle,
- Improving understanding of resistance mechanisms and transmission routes,
- Developing innovative diagnostics, therapies and prevention strategies,
- Expanding research infrastructure and capacity,
- Promoting the use and reuse of existing data,
- Accelerated translation of scientific findings into policy, practice and industry.

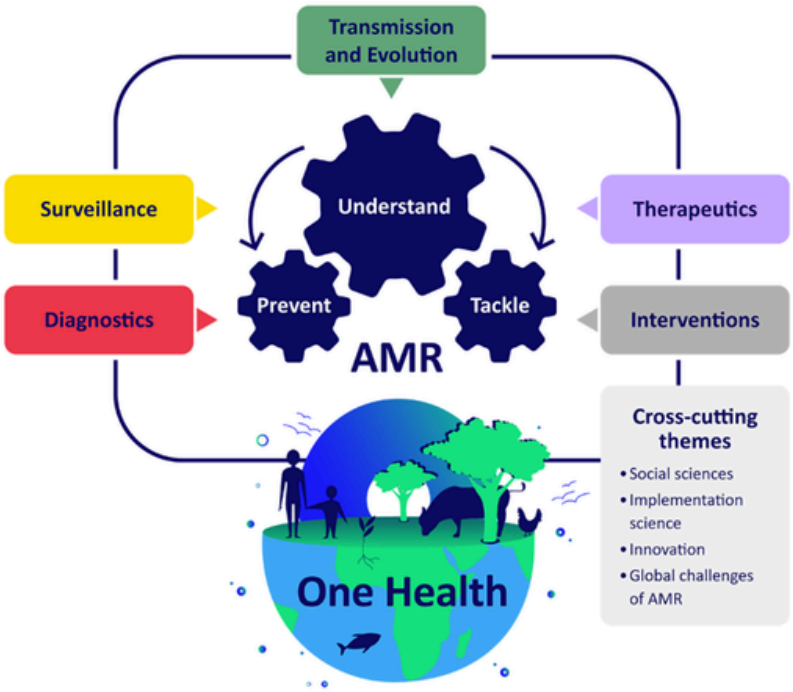

Figure 1: The EUP OHAMR thematic areas and cross-cutting themes. © www.ohamr.eu

General Assembly at AGES: Cooperation as the key

The partnership's first annual meeting at AGES in Vienna in March 2026, combined with the second General Assembly, brought together representatives from science, politics and administration and served as a platform for strategic coordination and professional exchange. In addition to meetings of the Scientific Advisory Board and the Strategy Council, working meetings for the individual work packages took place.

The focus was on the further development of a joint European strategy to combat AMR. It became clear that **no single country or institution is capable of tackling the AMR problem in isolation**. Rather, it requires coordinated, international approaches that pool individual resources and make sensible and effective use of synergies.

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General Assembly at the OHAMR Annual Meeting in Vienna, Austria © AGES 2026

AGES contribution to the partnership

AGES plays an active role within the EUP OHAMR and is involved in several work packages, particularly in the area of capacity building and knowledge transfer: More specifically, within the **'Strengthening Capacity for Sustainable AMR Research'** work package, a global analysis of capacity gaps in AMR research is being conducted under the leadership of AGES to serve as a basis for further development models. Additionally, the promotion of interdisciplinary collaboration and knowledge exchange, as well as the development and expansion of education and training programmes, are being managed as key tasks.

These activities make a significant contribution to establishing long-term and sustainable research structures in the field of AMR with international partners.

One Health as an Integrative Concept

A central feature of the partnership is the One Health approach, which takes into account the close interdependence of human health, animal health, and the environment.

Figure 2: One Health Concept *© www.ohamr.eu*

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Antibiotic resistance arises and spreads within a complex network:

- In humans through therapeutic applications,
- In animal husbandry through prophylactic or growth-promoting use,
- In the environment through wastewater from hospitals, agriculture and pharmaceutical production.

Resistance genes can be transferred between these sectors, thereby contributing to global spread. Taking these interconnections into account is crucial for the development of effective counterstrategies.

Outlook and need for action

To effectively contain the AMR crisis, several measures are required:

- Intensifying research into new antimicrobial agents,
- Development of rapid and cost-effective diagnostics,
- Improving surveillance systems,
- Promoting preventive strategies to reduce the use of antibiotics,
- Integrating scientific findings into policy-making processes.

The EUP OHAMR serves as a central platform for this purpose, linking research, regulation, industry and society.

Conclusion

The EUP OHAMR annual meeting 2026 at AGES highlights the importance of international cooperation in the fight against antibiotic resistance. Given the global scale of the problem, coordinated, cross-sectoral approaches are essential.

The partnership offers a structured framework for translating scientific findings into concrete measures and contributing to the long-term containment of AMR. Its success will depend largely on the extent to which research, innovation and implementation can be effectively combined.

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Medical Association of South East Asian Nations (MASEAN) Conference of 5 May 2026

Medical Association of South East Asian Nations

The 21st MASEAN Conference was held on 5 May 2026 at Panglao, Bohol, Philippines, in time with the Philippines' hosting of the Association of South East Asian Nations (ASEAN) Summit in Cebu, Philippines. The Philippines will be leading the MASEAN Council in the next two years under the leadership of Dr. Hector M. Santos Jr.

MASEAN aims to "promote closer ties among the national medical associations" of the ASEAN member states in its pursuit to support the attainment of the sustainable development goals through "mutual cooperation while maintaining the dignity and standards of the medical profession." (1).

MASEAN membership has increased again this year with the recent inclusion of the Association of Medical Doctors of Timor-Leste as an official member of MASEAN. They join Brunei Medical Association, Cambodian Medical Society, Indonesian Medical Association, Laos Medical Association, Malaysian Medical Association, Myanmar Medical Association, Philippine Medical Association, Singapore Medical Association, Medical Association of Thailand, and Vietnam Medical Association.

This year's Conference theme was: "A Regional Commitment to Physician Well-being and Climate-conscious Health Systems in Southeast Asia". The pre-event meetings by the MASEAN Group of Journals and Junior Doctors Network Meetings also revolved around a similar theme.

The Country Reports presented by delegates from Brunei Darussalam, Indonesia, Malaysia, Singapore, Thailand, Timor-Leste, Vietnam, and the host country, the Philippines, highlighted the need for regional cooperation, advocacy, and alignment to address identified gaps and barriers to physician mental health. As emphasised in one of the reports, "mental health among healthcare workers is no longer only a welfare issue; it is a workforce issue, a patient safety issue, and a health-system resilience issue" (2). From the proceedings, a Manifesto on Physician Mental Health and Environmental Stewardship (Bohol Manifesto) was adopted (3). The Bohol Manifesto commits the MASEAN to foster supportive work environments, address systemic stressors, and promote climate-conscious healthcare practices. Concrete actions stemming from the commitments will be presented at the upcoming MASEAN Meeting in Da Nang, Vietnam.

(1) MASEAN Constitution. Retrieved from https://masean.net/about-us/constitution, 27 May 2026

(2) Vietnam Medical Association Country Report: Why this topic matters now, Context of the 21st MASEAN Conference & Bohol Manifesto

(3) Bohol Manifesto will be released in full by the MASEAN Secretariat in the coming weeks

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Advancing Pharmaceutical Medicine through Pharmacometrics in Africa and the Middle East: The Tunisian Chapter Experience

Introduction: A Growing Need for Model-Informed Approaches

Pharmaceutical Medicine is rapidly evolving, driven by advances in data science, clinical pharmacology and regulatory innovation. In this context, pharmacometrics plays a central role in supporting model-informed drug development (MIDD) and precision medicine by integrating pharmacokinetics, pharmacodynamics and patient variability into quantitative frameworks. Today, pharmacometrics is considered a mandatory toolkit for decision-making in R&D, regulatory administration and clinical practice.

However, access to pharmacometrics training remains uneven, particularly in regions such as Africa and the Middle East, limiting its integration into clinical research and drug development. Addressing this gap requires not only education, but also the development of collaborative ecosystems aligned with the principles of Pharmaceutical Medicine.

The Emergence of the Tunisia Chapter: A Francophone Initiative

The Tunisia Chapter of Pharmacometrics Africa was established as the first Francophone chapter within the network, building on momentum generated through initiatives such as the Applied Pharmacometrics Training (APT) programme. This programme played a key role in connecting Tunisian professionals to the broader Pharmacometrics Africa community and catalysing the development of a structured local initiative.

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The Chapter brings together a core team of **10 members** from diverse backgrounds, including pharmacy, mathematics and biostatistics, with experience spanning academia, hospital practice, research and consulting. It also seeks to connect the Tunisian scientific diaspora across countries such as France, the United Kingdom and Switzerland, with each member contributing both their expertise and professional network.

The initiative has been supported by the **Faculty of Pharmacy of Monastir**, providing strong academic anchoring and supporting the development of structured educational activities. Its objectives are to **strengthen capacity in pharmacometrics**, promote model-informed approaches in drug development and clinical practice, and foster collaboration across academia, healthcare, industry and regulatory sectors, in close interaction with other PMX Africa chapters.

A High-impact Launch at the International Pharmaceutical Forum

The Tunisia Chapter was officially launched during the 24th edition of the International Pharmaceutical Forum, held in Tunisia in May 2025 and organised by the National Council of the Order of Pharmacists, through a dedicated roundtable workshop entitled:

“Pharmacometrics: Towards Therapeutic Expertise and Research & Development Opportunities in Africa.”

Designed to position pharmacometrics within Pharmaceutical Medicine, the session highlighted its role in drug development, clinical practice and research. It brought together a multidisciplinary panel covering key aspects of the field, from foundational concepts to modelling approaches and practical applications, including population pharmacokinetics and physiologically-based pharmacokinetic (PBPK) modelling.

The workshop gathered a diverse audience, including clinical pharmacology experts, regulators, academics and students, and was held in the presence of the Dean of the Faculty of Pharmacy of Monastir and senior pharmacology faculty members.

It concluded with the official announcement of the Tunisia Chapter and the launch of the next edition of a French-language online course in clinical pharmacology and pharmacometrics. The Chapter subsequently became involved in coordinating this educational initiative in collaboration with the Faculty of Pharmacy of Monastir and Pharmacometrics Africa.

This milestone marked a pivotal step in transforming awareness into structured engagement and fostering the development of pharmacometrics within Pharmaceutical Medicine in the region.

From Awareness to Action: A Francophone Training Initiative

Following this launch, the Tunisia Chapter translated its vision into action through the coordination of the second edition of a French-language online course in clinical pharmacology and pharmacometrics. The programme was structured around 12 comprehensive lessons, covering key concepts from fundamental principles of pharmacokinetics and pharmacodynamics to advanced

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modelling approaches and their applications in drug development and clinical practice. It brought together 16 international experts from academia, clinical research, industry and pharmacometrics consulting, reflecting the multidisciplinary nature of the field.

The initiative generated strong interest, with 319 participants registered from 25 countries, highlighting the growing demand for accessible pharmacometrics training in Francophone regions. This engagement was further supported by the Faculty of Pharmacy of Monastir and its Dean, who played a key role in disseminating the call for applications through their network of Francophone faculties across Africa.

The course combined structured learning with interactive live sessions, fostering active engagement, collaboration and knowledge exchange between participants and experts. It provided not only theoretical foundations but also practical insights into the implementation of model-informed approaches in Pharmaceutical Medicine.

Lessons Learned and Future Perspectives

The Tunisia Chapter experience highlights key enablers for advancing Pharmaceutical Medicine, including the importance of capacity building, language accessibility and multidisciplinary collaboration. It also underscores the need for practical, hands-on training to support the effective implementation of model-informed approaches.

Building on this momentum, the Chapter aims to expand its activities through workshops, webinars and strengthened collaboration with other African and Middle Eastern chapters, fostering a more connected and sustainable pharmacometrics ecosystem. In parallel, the chapter team initiated meetings with local practitioners to better understand unmet needs in routine care and clinical research. These discussions helped to characterise priorities where pharmacometrics could have a tangible impact, such as dose optimisation in major burn patients or in special population such as paediatric, geriatric, critically ill, and other vulnerable patient groups. In addition, the Chapter seeks to develop competitive research projects supported by major international funding bodies, including Horizon Europe and the NIH, in order to consolidate its scientific output and enhance its global visibility.

Overall, this initiative illustrates how targeted education, combined with collaborative networks, can contribute to a more inclusive and impactful approach to drug development, support regulatory decision-making, clinical research and therapeutic optimisation.

Photo 1: *Professor Myriam Razgallah Khrouf presenting the Tunisia Chapter and its educational activities during the workshop at FPI 2025. The presentation highlighted the Chapter's mission, faculty network, and contribution to the development of clinical pharmacology and pharmacometrics training in the Francophone region.*

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Photo 2: *Group photo of the workshop moderators, senior academic leaders in pharmacology, including the Dean of the Faculty of Pharmacy of Monastir, and the founding members of the PMX Africa Tunisia Chapter during the 24th International Pharmaceutical Forum (FPI 2025) in Tunis.*

Photo 3: *Official flyer of the workshop "Pharmacometrics: Towards Therapeutic Expertise and a Dynamic Research & Development Ecosystem for Creating Opportunities in Africa", organized during the 24th International Pharmaceutical Forum (Tunis, May 2025). The workshop brought together Tunisian and international experts to introduce key concepts in pharmacometrics and promote capacity building initiatives across Africa.*

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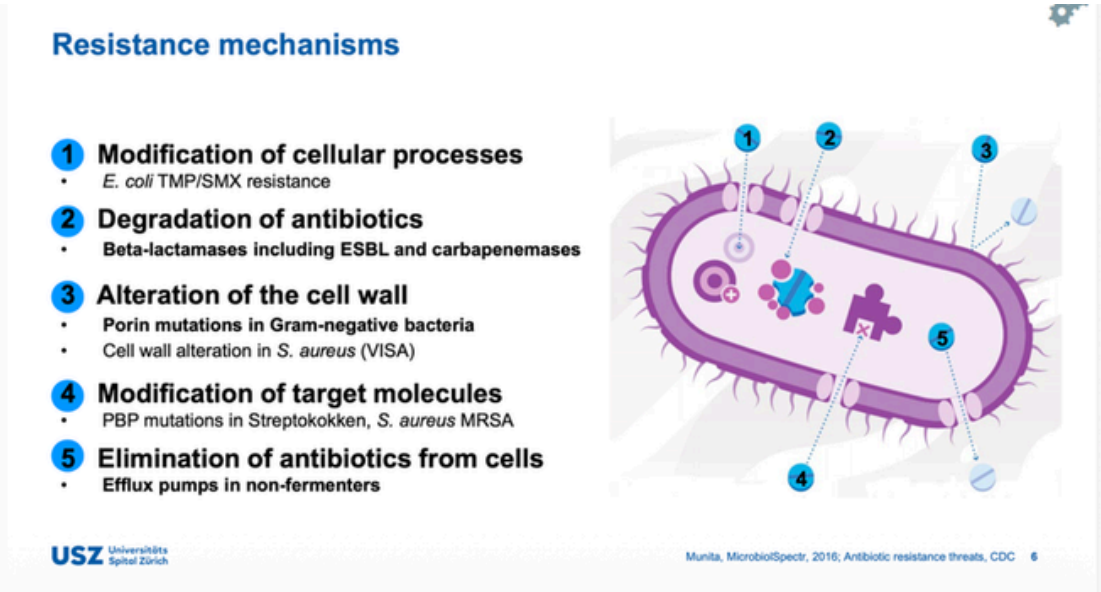
Summary of the IFAPP Webinar of 26 May 2026

Are we running out of antimicrobials?

Speaker:
Professor Silvio Brugger FESCMID*, 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
*Fellow of the European Society of Clinical Microbiology and Infectious Diseases

Professor Brugger started his presentation with the description of resistance mechanisms:



and pointed out the challenges which have to be faced in a hospital environment:

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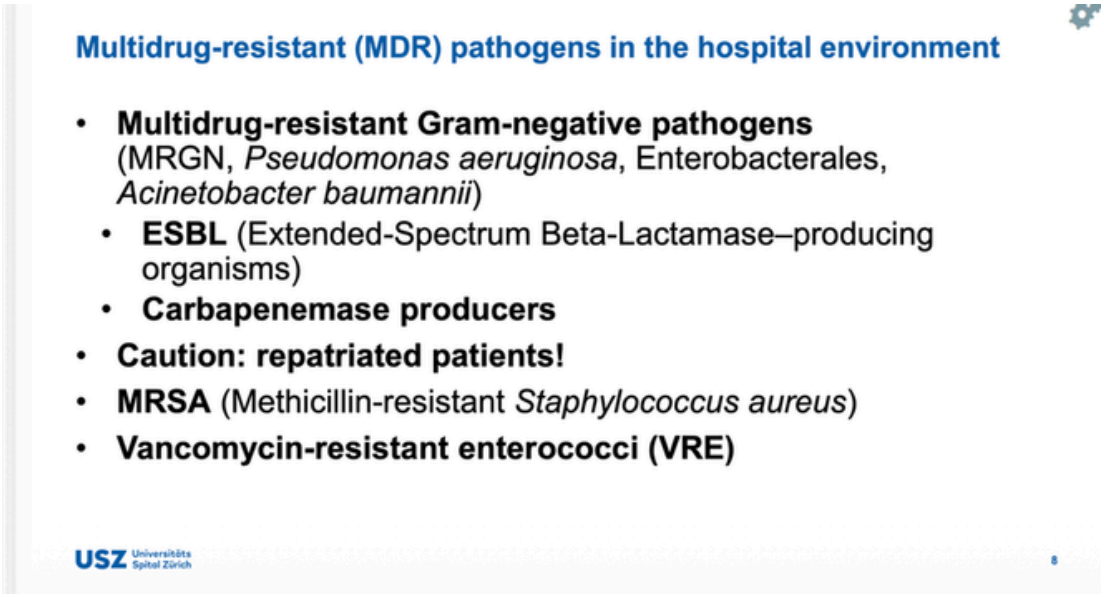
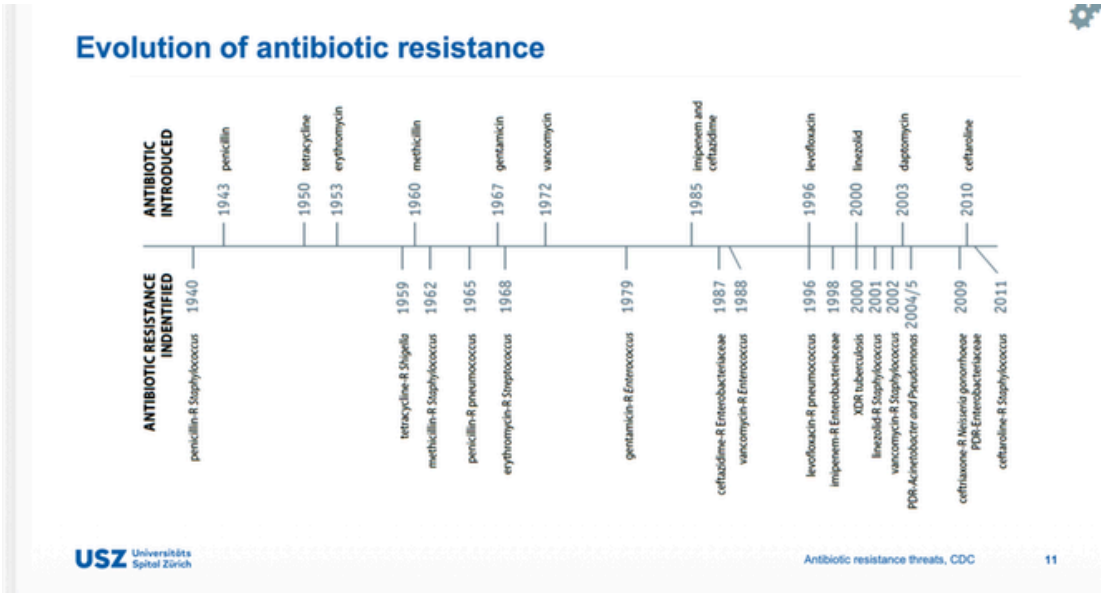


In his presentation Professor Brugger gave an overview of the evolution of antibiotic resistance from the start of antibiotic treatment with penicillin:



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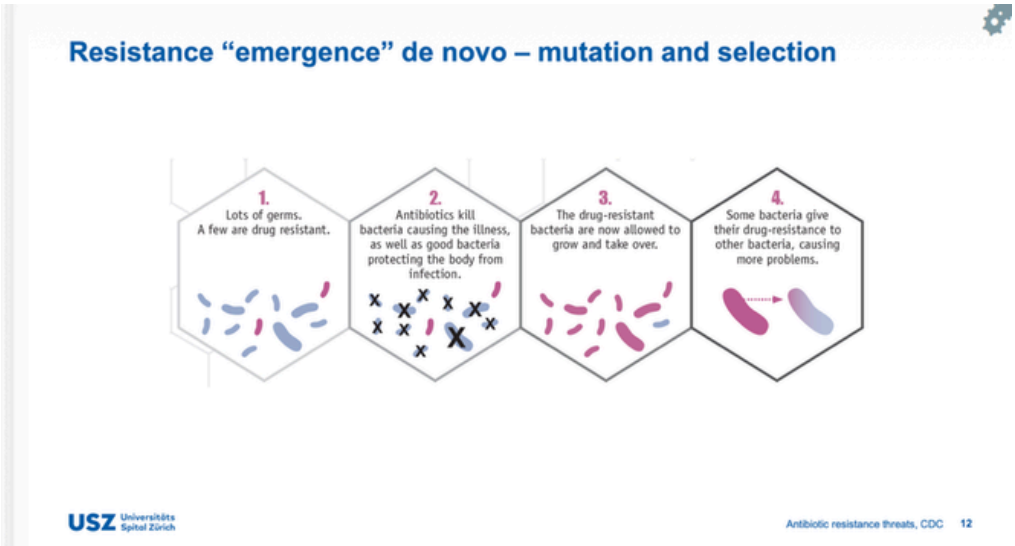
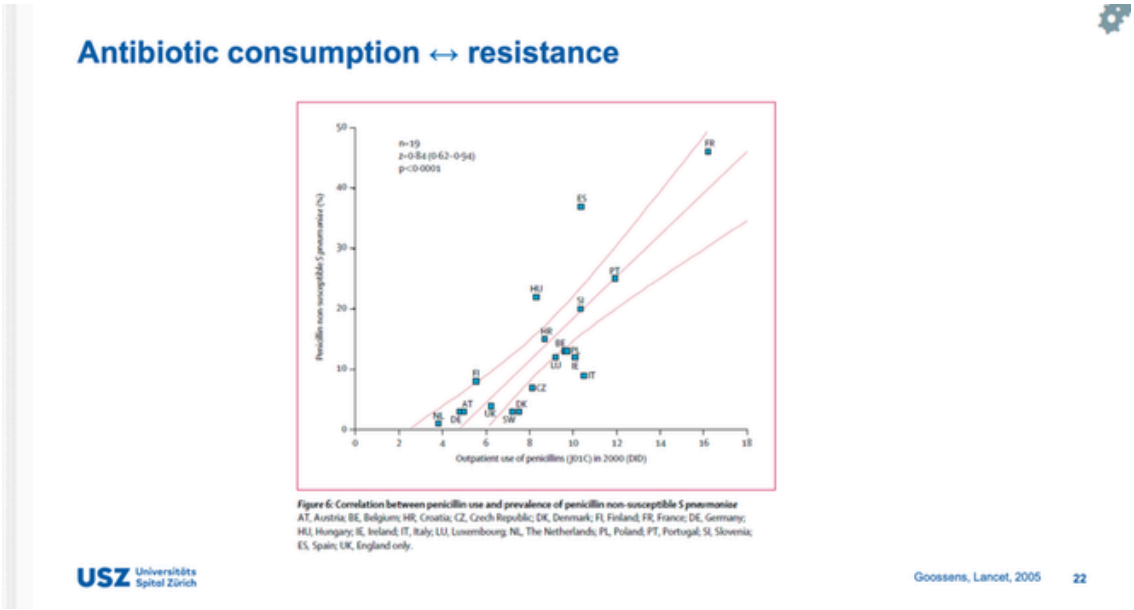
and the underlying mechanisms of resistance:



Professor Brugger pointed out the correlation between antibiotic consumption and development of antimicrobial resistance and mentioned that not only the relationship between patients' treatments have to be taken into account but also environmental burdens in the broadest sense (plants, animals, medicinal product production):



He continued by presenting the demanding task to find the optimal treatment for patients with an infection in the daily practice of a hospital:

- Finding the optimal medicinal product under timely pressure due to the health condition of the patient,
- Availability of the medicinal product (approval in country, launch in small markets, reimbursement).

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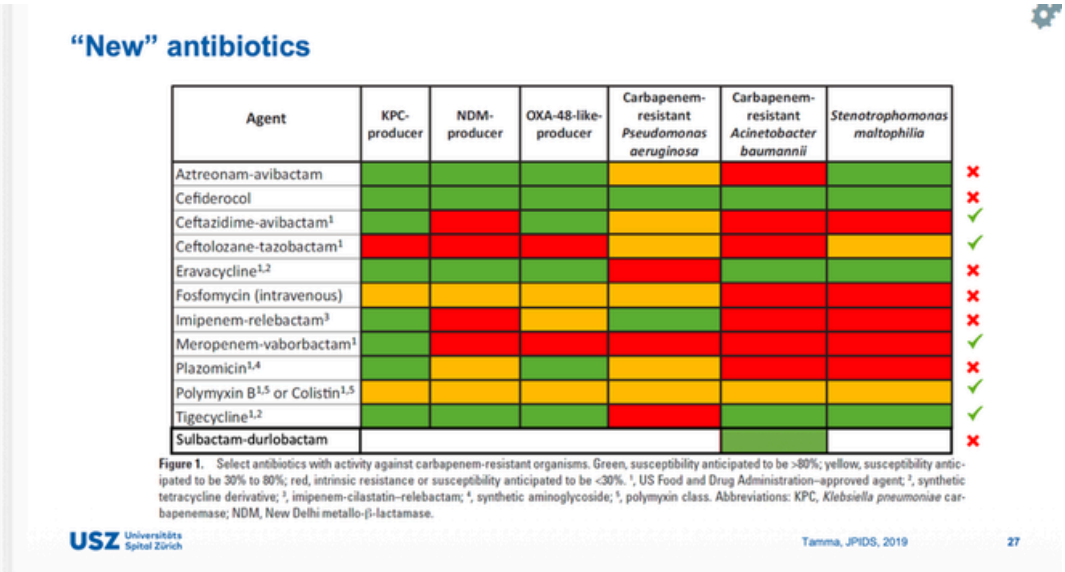
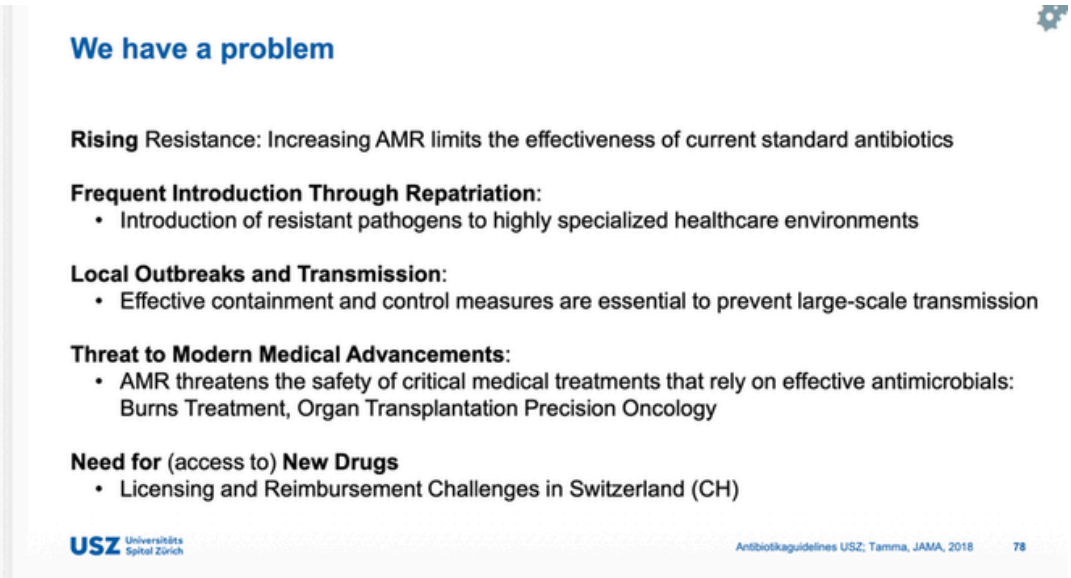


Professor Brugger presented several patient cases by describing the complication of identifying the optimal treatment for the individual patient (detailed information to be found in the recording of the webinar).

He concluded:



The full set of slides and the video recording can be found under this link:
https://youtu.be/y9rKvfYTkOQ

Authors:
Birka Lehmann, MD PhD, Chair of IFAPP's Education and Certification Working Group (ECWG),
Prof. Dr med. Silvio Brugger, speaker/presenter of the webinar

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

Click here to register

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Free Webinar: “Mentorship in Pharmaceutical Medicine: The SIMeF Experience in Italy” - 9 July 2026, 12:00 noon CEST

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2026

IFAPP *Free webinar*

The webinar will take place on 09 July 2026 at 12.00 noon CEST and will present the Mentorship Programme developed by the Italian Society of Pharmaceutical Medicine (SIMeF), designed to support personal and professional growth through structured mentor–mentee relationships.

The programme, successfully implemented in 2025, demonstrated the value of mentoring as a tool for career development, knowledge sharing, and professional orientation. Built around participants' needs, it includes a tailored matching process and fosters continuous dialogue, enabling participants to enhance both technical competencies and soft skills such as communication, decision-making, and networking.

The webinar will also highlight the mutual benefits for mentees and mentors, the key outcomes of the initiative, and the launch of the 2026 edition. Finally, it will explore the potential for scaling the programme at an international level within the IFAPP network, promoting structured mentoring practices in Pharmaceutical Medicine.

SPEAKERS

Francesco Buttl

After graduating in Biotechnology, I began my professional career in the pharmaceutical industry, gaining progressive experience, holding increasing roles and responsibilities in clinical research and medical affairs. In detail here are the roles I covered: Medical Information Specialist, Clinical Research Associate, Clinical Trial Manager, Medical Advisor, Head of Local Operations, Medical Manager.

I am deeply passionate about research, innovation, and healthcare transformation. I strongly believe in generosity, the quality of relationships, and the ability of networks to generate knowledge, trust, and impact. I am currently responsible for Clinical Development Operations at Boehringer Ingelheim Italy. I am also a member of the IFAPP Communication Working Group.

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Marisa Le Donne

I am a clinical research specialist with experience in clinical development-operations and medical writing, currently expanding expertise through a job enrichment in Medical Affairs. I have a PhD in Pharmaceutical Sciences, with a background in research and medical writing prior to clinical research.I am experienced in complex, international environments and in cross-functional collaboration supporting clinical development and strategic initiatives. I have atrong interest in real-world evidence, scientific strategy, and drug development and I am actively involved in SIMeF and contributing to the Pharmaceutical Medicine community as the IFAPP Delegate for Italy.

I am currently a Clinical Trial Manager at Boehringer Ingelheim Italy, a current member of the IFAPP Young Professionals Working Group and a former coordinator of the SIMeF Young Professionals Working Group

Click here to register

After registering, you will receive a confirmation email containing information about joining the webinar.

Time Schedule

06:00 AM - 07:00 AM EST
10:00 AM - 11:00 PM GMT
12:00 NOON - 01:00 PM CEST
07:00 PM - 08:00 PM JST

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Upcoming Free Webinars

Mark Your Calendar with the Upcoming Free Webinars:

- 19 June 2026 - Level Up Your Career: The Mentorship Advantage
  Click here to register.
- 9 July 2026 - Mentorship in Pharmaceutical Medicine: The SIMeF Experience in Italy
  Click here to register.

THE FLAG

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