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INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

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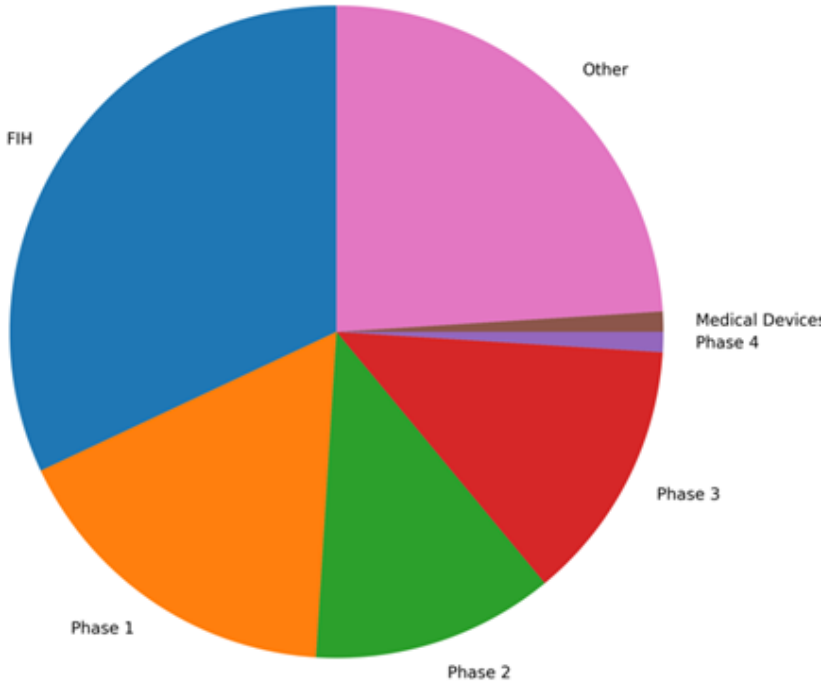
Why Heading Down Under for Clinical Trials

Australia has established itself as one of the world's most efficient, trusted and attractive jurisdictions for the conduct of clinical trials. From a regulatory affairs perspective, the country offers a distinctive and favourable model, with a framework based on Human Research Ethics Committee (HREC) review and oversight and supported by supervision from the Therapeutic Goods Administration (TGA), the Australian regulator. This model has enabled Australia to attract substantial international investment, particularly in early-phase research.

Figure 1: Distribution of Clinical Trials in Australia by Phase (2024 estimate)



Clinical trial activity in Australia has grown significantly over the past two decades. Approximately 1,850 clinical trials, involving around 90,000 participants and an expenditure estimated at around AUD 1.6 billion, commenced in Australia in 2022 alone. The country's international profile also continues to strengthen. In 2024, two-thirds of overall trials, and three-quarters of early-phase trials reviewed by the leading Australian HREC, were funded by international sponsors. Australia represents a very attractive jurisdiction for sponsors seeking expedited study initiation without compromising data integrity and global regulatory acceptance.

Australia's population further enhances its attractiveness for multinational development strategies. With 30% of the population born overseas, and up to 50% having at least one parent born overseas, Australia is amongst the most ethnically diverse countries in the world, ensuring the recruitment of a heterogenous patient population.

Data generated in Australian trials are accepted by both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), and Australian study sites are routinely included within global development strategies. Mandatory registration of all trials in the Australian New Zealand Clinical Trials Registry (ANZCTR) ensures transparency.

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Australia's Clinical Trials Regulatory Framework

Clinical trials in Australia are conducted under two regulatory pathways:

- The **Clinical Trial Notification (CTN) scheme** is the pathway used for the vast majority of trials conducted in Australia. Primary responsibility for scientific and ethical review rests with accredited HRECs. Once HREC and institutional authorisation are obtained, the sponsor notifies the TGA. The TGA does not undertake an independent evaluation of the quality, preclinical and clinical data package before the trial commences. Instead, the responsibility for risk assessment and ethical justification lies with the reviewing HREC and the approving institution. This approach significantly reduces administrative burden and shortens trial commencement timelines.

- By contrast, the **Clinical Trials Approval (CTA) scheme** requires formal TGA evaluation and approval prior to trial initiation. This pathway is mandatory only for higher risk investigational biological products (Class 4 biologicals), such as live animal cells, tissues or organs, pluripotent stem cells, human cells or tissues modified to artificially introduce a not intrinsic function. Under this pathway, the TGA undertakes a thorough scientific assessment of quality, safety and nonclinical data prior to granting authorisation.

While the CTN pathway is typically associated with First-in-human (FIH) studies, the regulatory pathway depends on the product classification, and not on the trial Phase. The efficiency of the CTN pathway has become one of Australia's key competitive advantages.

The Role of HRECs

HRECs play a central role in the Australian system, as they are responsible both for ethical review and scientific assessment, including evaluation of the risk–benefit balance, and participant protection. Bellberry, a not-for-profit (NFP) organisation, is Australia's largest independent ethics provider and reviews approximately 40% of CTN clinical trials

A single ethical review can support multi-centre trials, and local governance processes address site-specific operational matters. Since Australia is a federation, governance processes may vary across states, requiring careful coordination across sites.

Therapeutic Strength

Oncology accounts for more than 25% of registered trials, reflecting both disease burden and strong research infrastructure in cancer centres across the country. This ensures that HRECs and investigators are experienced in complex and adaptive trial designs, and biomarker-driven protocols. Neurology, dermatology and haematology also represent therapeutic areas with high clinical trial activity.

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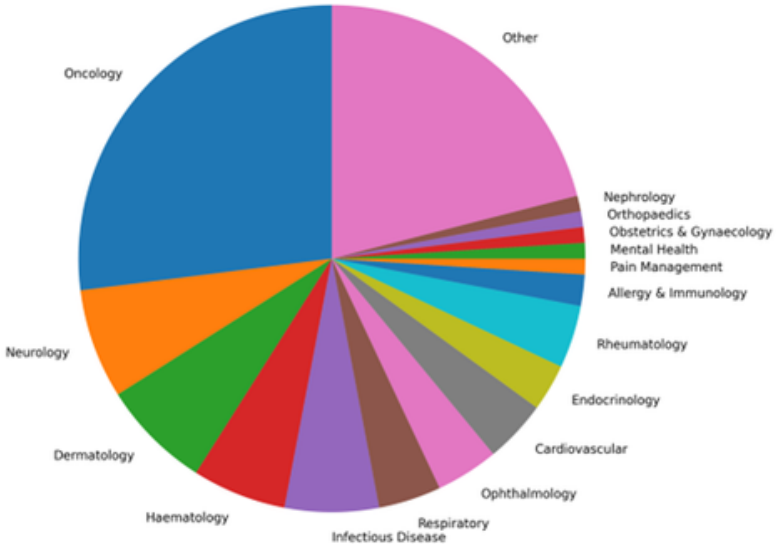
Figure 2:Distribution of Clinical Trials in Australia by Therapeutic Area (2024 Estimate)



Conclusion

Australia's favourable regulatory environment balances regulatory oversight with operational efficiency, enabling rapid trial initiation without compromising data integrity or participant safety. Combined with its strength in early-phase research and excellent medical infrastructure, this has cemented Australia's international reputation as a global centre for innovative drug, biologics and device development.

References/Abbreviations:

ANZCTR, Latest Update of the Clinical Trials Landscape (2006-2020), 2022
Bellberry Limited, Clinical Trial Activity Report, 2024
MPT Connect, Australia's Clinical Trials Sector, 2024
GAICD: Graduate of the Australian Institute of Company Directors
MMPP: Member MedTech and Pharmaceutical Professional
MAPA: Member Medical Affairs Professionals of AustralAsia

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Pharmacovigilance in Pregnancy and Lactation: Towards a New Paradigm of Data and Responsibility

The safety of medicines during pregnancy and lactation is of paramount clinical and regulatory importance, significantly impacting patients and the entire healthcare system, given that up to 90% of women may find themselves in need to take medications at some stage.

The difficulty in obtaining robust drug safety information during pregnancy and lactation is primarily due to the traditional exclusion of these populations from clinical trials; less than 0.4% of studies include pregnant women, and less than 0.1% include breastfeeding ones. This scarcity of data in both the pre- and post-marketing phases leads to missing information on the safety of drugs when they are introduced to the market. Furthermore, significant physiological modifications, including changes in the volume of distribution, organ perfusion, and renal/hepatic functions, complicate drug absorption, metabolism, and elimination, making rigorous benefit-risk assessment for the mother and child challenging.

Pharmacovigilance (PV) in pregnancy and lactation is therefore an area which demands even greater attention and rigour and necessitates multidisciplinary discussion and attention from all stakeholders involved in pregnant patients' journey, to provide the best possible support in medical decision-making for healthcare providers and patients.

Considering such a need, the SIMeF Pharmacovigilance (PV) (1) working group organised in December 2025 a webinar, "Pharmacovigilance in Pregnancy and Lactation," with the patronage of the European Patients' Academy on Therapeutic Innovation (EUPATI) and the Italian Association of Women Doctors (AIDM): it brought together professionals from pharmaceutical companies, clinicians, teratology experts and patient representatives to discuss one of the most sensitive areas in medicinal product safety.

Nearly seventy years after the tragic thalidomide case which, with its teratogenic outcomes, marked the birth of modern PV - pregnancy and lactation remain delicate clinical scenarios. The historical echo of the thalidomide tragedy serves as a crucial warning, urging rigorous evaluation of the benefit-risk ratio of medicines, with particular attention to early signals. Multidisciplinary discussion is of the utmost importance to advance knowledge on this delicate topic.

Medical and physiological aspects were clearly explained by Dr A. Lucchese (from "S. Spirito" Hospital, Rome) who illustrated the main physiological changes occurring during pregnancy and lactation. Fear of foetal effects can lead to limited drug prescription or sub-optimal dosing, while false perceptions of "innocuousness" can support excessive prescribing. Changes in volume of distribution, organ perfusion, renal and hepatic function, along with transplacental transfer and diffusion into breast milk, alter drug absorption, distribution, metabolism, and elimination. Furthermore, differences in

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metabolism between mother and neonate add complexity. In this context, the clinician plays a fundamental role in evaluating dose and timing and planning targeted follow-ups.

Dr M. Gallo from the Anti-Poison Center in Bergamo presented the Teratology Information Service (TIS), active since 2002 and one of ten present in Italy. Its mission is to provide training and information on drugs in pregnancy. Its activity has grown significantly (e.g., consultation requests increased from 2000 to 2024, with a prevalence of questions about antibiotics). The TIS assesses drug exposure risk in pregnancy and lactation, estimates teratogenesis risks, suggests prenatal diagnostics, and proposes therapeutic alternatives in coordination with the physician. The TIS participates in multicentre studies, including those initiated during the COVID-19 pandemic.

Therapy in these conditions is often avoided due to fear of risks, sometimes replaced by dietary supplements mistakenly considered harmless. In collaboration with the University of Milan-Bicocca, the centre is analysing data on pregnancy and lactation, observing possible effects in the child still under evaluation. From 2021 to 2024, the TIS conducted an active PV observational study, in agreement with the Italian Drug Agency (AIFA): out of the 2,670 patients enrolled (despite a 27% drop-out), 1,973 responded to follow-ups, highlighting drugs with a higher incidence of Adverse Drug Reactions (ADRs). The reports were entered into the National PV Network and are available in EudraVigilance.

Dr C. Casino (Italian PV Responsible for Servier, SIMeF PV working group member) and Dr A. Bodini (Italian PV Responsible for Pierre Fabre, SIMeF PV working group member) outlined the pharmaceutical company's viewpoint on managing PV data in pregnancy and lactation, detailing the regulatory framework for collecting and managing adverse event reports, and highlighting strategies to improve drug safety in this setting. Women who are pregnant or breastfeeding are, as reported above, traditionally excluded from clinical studies, nevertheless, drug exposure is a common clinical routine. According to the IMI CONCEPTION (2) study, up to 90% of women take medication at some stage during pregnancy or lactation. While many of these drugs are safe, only 3.7% of medicines are explicitly labelled as safe for use in that scenario. Such a lack of information fuels anxiety, which can lead to the autonomous discontinuation of treatment for pre-existing or pregnancy-related chronic conditions – a choice made by one out of three women, with potentially severe consequences for their own health.

The majority of current data on drugs in pregnancy and lactation comes from the post-marketing phase. The quality of data collection and the completeness of follow-ups are crucial for evaluating causality, maternal effects, potential teratogenicity, and safety during lactation. Marketing Authorization Holders (MAH) report available teratogenicity data in the Risk Management Plan (RMP) and present a full plan. During her speech, Dr A. Bodini detailed the PV challenges for medicines with potential embryofoetal toxicity, citing GVP (3) references: Module 5 on RMP, Module 16, and the Addendum on Risk Minimisation Measures (RMMs). Risk is defined as the statistical probability of an unfavourable clinical outcome with a causal relationship between the drug and the event, which may be identified

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or potential. Important risks are those that can significantly impact the benefit-risk ratio and must be monitored, also considering "missing information" - knowledge gaps with significant potential impact, analysed in the RMP.

The RMP describes PV activities and interventions to identify, characterise, and prevent risk. During characterisation, it is essential to define the pregnancy phase in which the risk manifests and how the MAH intends to prevent it (e.g., PASS (4) studies, follow-up questionnaires, registries). Beyond routine measures, the Summary of Product Characteristics (SmPC), labelling (including pictograms), Patient Information Leaflets (PIL) - additional RMMs are required in the presence of identified embryotoxicity: prevention of exposure at conception or in utero, risk minimisation, and promotion of awareness (for healthcare professionals and patients). The target audience must be agreed upon with the regulatory authority (prescribing specialists, general practitioners, pharmacists, gynaecologists, paediatricians, women, men, adolescents, potential donors). Measures must be calibrated to the phase of exposure and sometimes integrated into pregnancy prevention programmes.

Promoting awareness and communicating risk is essential to maintain adherence to RMMs. Effective doctor-patient dialogue is needed on embryofoetal risk, therapeutic alternatives, and actions to take in case of exposure. Dedicated materials - consent forms, patient cards, checklists, questionnaires - can facilitate informed decisions. Procedures and standardised forms support the collection of quality data, although follow-ups are often challenging.

Regulatory Evolution and Risk Management

To address that context, the new ICH E21 (5) guideline (scheduled for implementation in 2028) aims to provide a globally accepted framework and best practices to enable the inclusion and/or maintenance of pregnant and breastfeeding women in clinical trials. It will establish principles and practices to ensure the collection of a sufficiently robust set of safety, efficacy, and/or pharmacokinetic data, allowing for more informed clinical decisions on the use of medicines: the guideline encourages proactive planning throughout the entire experimental product development process, with timely consultation of regulatory authorities and all stakeholders, including patients.

Additionally, a new module of the Guideline of Good Pharmacovigilance Practices - product- or population-specific considerations III: pregnant and breastfeeding women (6), has just been published: this document provides guidance to applicants/MAHs and competent authorities on PV practices specific to the use of medicines in pregnant and breastfeeding women. The goal is to ensure that risks associated with drug use in these populations are adequately identified, characterised, and minimised, without unnecessarily depriving women of useful treatments. The document emphasises the need for a proactive, evidence-based approach, acknowledging the challenges related to data scarcity and the physiological specificities of these populations.

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Signal Detection and Adverse Reaction Types

The scarcity of suspected adverse drug reactions (ADR) reports in pregnant women can significantly affect signal detection in this patient population. Conversely, the lack of specific indicators for pregnancy-related case reports complicates the retrieval of such information from PV databases. To address this, the European Medicines Agency (EMA) and the Uppsala Monitoring Centre (UMC) have developed algorithms, applied to EudraVigilance (7) and VigiBase (8), to identify pregnancy-related reports with high specificity in large databases, outperforming current MedDRA (9) Standardised Queries.

Regarding the type of ARs collected during pregnancy, a French (10) study highlighted a higher frequency of serious ARs in pregnancy (anaphylaxis, cardiac and vascular disorders, hepatobiliary issues, medication errors) in the national PV database, while a study in India (11) found common ADRs from antibiotics with dermatological reactions.

Round Table and Future Directions

The round table discussion, which included Dr S. Gainotti (ISS Bioethics Unit), Dr C. Schiavone (Campania Region Pharmacovigilance Center), and Dr P. Kruger (EUPATI), thoroughly explored risk management associated with therapy use during pregnancy. While pregnant women are increasingly aware of potential drug risks, general knowledge on the subject remains limited. It is essential to explore how to improve patient awareness and involvement in therapeutic risk management by engaging clinicians in the discussion.

The lack of active patient involvement in creating educational materials contributes to this gap. Current materials often use incomprehensible language, making it difficult for patients to fully understand the information. It is crucial to develop user-friendly content and involve patients to ensure that information is clear, up-to-date and pertinent.

Furthermore, self-reporting of adverse reactions is crucial. Patients need to be informed about the appropriate channels for reporting ARs, even minor ones, which can significantly impact their quality of life. Communication must be clear and accessible, not limited to the physician.

Another critical aspect is the low participation of pregnant and breastfeeding women in clinical trials. EU Regulation 536/2014 (12) and the new EMA guidelines emphasise the importance of including these vulnerable populations in clinical studies. It is necessary to improve the collection of real-world data, involving not only patients but also caregivers, to ensure more effective risk management.

Communication of drug risks in pregnancy is often influenced by information available on social media: these channels can provide useful information, but they also spread misinformation. It is vital that regulatory agencies and scientific societies use social media to communicate evidence-based information and combat fake news. Patients often feel closer to other patients than to their doctor; therefore, patient associations are fundamental in providing support and distributing reliable information in synergy with healthcare professionals. Pharmacists also represent a key figure in therapeutic risk management, as they have direct and immediate contact with patients: investing in pharmacists' training is essential to ensure they can provide accurate and timely information. Moreover, effective networking between all involved specialists is necessary to ensure fluid and timely communication.

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Finally, to better understand the patient journey, the existence of interoperable databases is desirable, a feature currently absent but recommended, for example, by the World Health Organization for anti-HIV (13) drugs. While there is still much work to do in this area, patients can play an active role in data collection even after childbirth, acting as a link between different information sources.

Dr Kruger stressed that patients are willing to provide useful information, but the process and pathway must be simplified to facilitate this participation. The future promises a qualitative leap if accompanied by: broader inclusion in clinical studies; systematic collection of real-world data; system interoperability; targeted RMMs; clear communication between physicians and patients; training of clinicians and pharmacists and support from qualified services like the TIS presented by Dr Gallo.

Behind every number, 140 million births annually worldwide, there are complex clinical choices and real lives: Pharmacovigilance, in this context, is not merely regulatory compliance, but a collective responsibility, a public health project, and an informed practice of care centred on the safety of the mother and child.

Acknowledgements
Thank you to all SIMeF ETS PV Working Group members: they support SIMeF activities with passion to increase awareness on PV topics and to create a culture that will help the safe management of medicines.
Thank you to my IFAPP PV Working Group colleagues for support and work done together.

Abbreviations/References:

1. SIMeF https://www.simef.it/
2. IMI Conception: ConcePTION | IHI Innovative Health Initiative; https://www.ihi.europa.eu/projects-results/project-factsheets/conception
3. GVP: Good Pharmacovigilance Practices
4. PASS: Post-authorisation safety studies
5. ICHE21: https://www.ema.europa.eu/en/ich-e21-guideline-inclusion-pregnant-breastfeeding-individuals-clinical-trials-scientific-guideline
6. http://www.ema.europa.eu/en/documents/scientific-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-final-considerations-pregnant-breastfeeding-women-their-children-exposed-utero-or-breastmilk_en.pdf
7. Eudravigilance:https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance
8. Vigibase https://who-umc.org/vigibase-data-access/about-vigibase
9. MedDRA: https: www.meddra.org
10. Balon M, Tessier S, Damase-Michel C, Cottin J, Lambert A, Thompson MA, Benevent J, Lacroix I. Adverse drug reactions in pregnant women: Do they differ from those in non-pregnant women of childbearing age? Therapie. 2023 Mar-Apr;78(2):165-173. Epub 2022 Nov 28. PMID: 36517304
11. Rani N. Pattern of Adverse Drug Reactions among Pregnant Women and Pediatric Patients in a Tertiary Care Hospital. Curr Drug Saf. 2023;18(2):190-195. PMID: 35379160
12. EU Regulation 536/2014: https://www.eur-lex.europa.eu/eli/reg/2014/536/oj/eng
13. HIV: human immunodeficiency virus

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Should Swiss Medicine Go Viral?

Phage therapy has been used successfully to treat patients with chronic antibiotic-resistant infections. In most countries, there are no approved phage drugs for human patients, but phages, also called bacteriophages, can be used as a last resort treatment. This happens very rarely in Switzerland – unlike in countries like Belgium or France that have facilitated access to this therapy. The project Forum Phagentherapie (1) is fostering a public debate if this should happen in Switzerland, too.

The discussion during the Forum event in Basel was captured graphically by Michael Meier, aka Denkpinsel.“ https://michaelmeier.ch/

It can be assumed that most of the Swiss public know about antibiotic resistance. However, it is much less certain how well people are informed about phage therapy. That is why the team of the Forum Phagentherapie has come up with a two-stage approach to enable an informed debate. Stage one consists of a half-hour documentary discussing phage therapy in Switzerland.

This documentary follows a patient who has been treated in the Geneva University Hospitals (2). The film familiarises the audience with the therapy and its most important aspects, including status of evidence, opportunities and hurdles. Stage two consists of four public Forum events in which the film is screened, followed by a discussion by a panel of experts with the audience. Workshops in various schools, a campaign in social media, and the website phagenforum.ch (1) are supplementing this setup by providing complementary information and targeting additional audiences.

Packed venue during the Forum event in Basel

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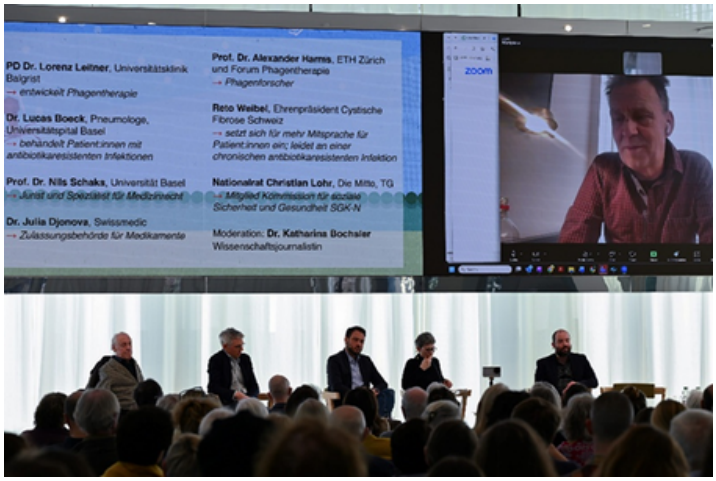

Part of the expert panel with Reto Weibel participating via video link from hospital

Two of the Forum events have taken place, one in Basel (31 January 2026) and the other one in Lenzburg (14 February 2026). In both cases, the venues were packed and the audience participated actively during the 2.5 hours of discussion (3). One of the experts was Reto Weibel, Honorary President of the Swiss Cystic Fibrosis association and himself affected by the disease. He also suffers from a chronic pulmonary infection and would like to be treated with antibiotics to improve his deteriorating health.

However, Reto Weibel is refused treatment because his treating doctors want to keep the two remaining, i.e., not yet used, antibiotics as a last resort. Reto Weibel has also been refused phage therapy as there are still two effective antibiotics available, creating a catch-22 situation that leaves him with slowly deteriorating health but no access to additional treatment for his pulmonary infection. Reto Weibel forcefully pleaded for a stronger involvement of patients in deciding which treatments they have access to. At the Basel event, it became especially obvious how precarious his situation is: he could not participate in person but had to use a video link from a hospital where he had to be admitted a few days before. The other participating experts (4) in the panel sympathised with Reto Weibel, and they emphasised the need to develop treatment alternatives for chronic infections and the potential of phage therapy. Prof. Dr Alexander Harms, a phage researcher at ETH Zurich (Federal Institute of Technology Zurich); http/ethz.ch/en.html) and co-lead of the Forum Phagentherapie, added that the extent of this need is probably underestimated: As the patient population suffering from resilient bacterial infections is very diverse and fragmented, its size may not be recognised to its full extent by health system stakeholders and society.

An interesting information surfaced during the discussion in Basel from the audience: A law expert clarified that the often-held assumption that the Swiss rules regarding last resort treatments impose a strict limit of no more than 3-5 treatments done by a physician or a hospital per year is wrong. The expert used to be a member of the Ethics Committee of the Canton of Zurich, and she said that, based on past practice, a number of 20 treatments would pose no problem.

Dr Julia Djonova from the Swiss regulatory agency Swissmedic (http://www.swissmedic.ch) said that it is paramount to obtain evidence of safety and efficacy of phage therapy from clinical trials. She emphasised that Swissmedic is supporting Swiss phage therapy researchers and clinicians in designing clinical trials. The moderator of the debate, Dr Katharina Bochsler, pointed to a gap between the great need for alternative treatments for chronic infections that exists today and the fact that it will take a considerable amount of time until a clinical trial can be successfully completed. Reasons for this are that clinical trials need investments of at least several tens of millions of Swiss Francs – a scale that is difficult or impossible to achieve for academic institutions or small companies that typically are active in phage therapy development. This was echoed by Prof. Dr Thomas Kessler

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who is working with his team at Balgrist University Hospital in Zurich (http://www.balgrist.ch) on phage therapy and is currently preparing a clinical trial.

One possibility to bridge this gap would be to adapt some of the approaches used by other countries like Belgium, France or Australia to make phage therapy accessible for patients who are not confronted by an immediate fatal outcome. The broad presence of expertise on the panel – from research to Clinical, Law and Health Policy – allowed to discuss a variety of possible approaches. The politicians outlined necessary political steps, including clarification of the regulatory situation and the development of treatment capacity. The audience gave clear indication that a majority would support such steps, both by taking the floor and by voting via an online tool: On a scale from 0 ("do not agree at all") to 5 ("agree completely"), the statement that Swiss politics should facilitate access to phage therapy and create treatment capacity obtained a vote of 4.4.

This is something that National Councillors Christian Lohr (on the panel in Basel) and Farah Rumy (Lenzburg) can take to the Swiss parliament for further discussions. Obviously, politics does not work as quickly and directly as that. But both politicians stressed the need to find a way forward and their interest in helping to do that. After the event, all the participants on the panel as well as many in the audience emphasised how valuable the dialogue has been so far. There will be two more similar events in Zurich (09 May 2026) and in the French -speaking part of the country (30 May 2026). They will provide opportunities for more dialogue and to identify concrete options to act.

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(1) Phagenforum: https://phagenforum.ch. The project is funded by the Agora programme of the Swiss National Foundation SNF (Schweizerischer Nationalfonds; (http://www.snf.ch/en/JnT2xEAERCgO8qQc/funding/science-communication/agora)
(2) The film (with subtitles in English) can be viewed at www.youtube.com/playlist?list=PLgDHliTu1pwGY7AdXNm9YAmzewLTetONy. It was funded by the Swiss Academy of Sciences (SCNAT; scnat.ch/en). The case narrated in the film was described in Köhler T, Luscher A, Falconnet L, et al. Personalized aerosolised bacteriophage treatment of a chronic lung infection due to multidrug-resistant Pseudomonas aeruginosa. Nat Commun. 2023;14(1):3629. doi:10.1038/s41467-023-39370-z
(3) The forum in Lenzburg was streamed live. The video can be accessed at www.youtube.com/@phagenforum
(4) Complete information about the panels' experts is available at https://phagenforum.ch/events/

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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)

Dialogue between European and Japanese patient groups

Two members of EUPATI (European Patients' Academy on Therapeutic Innovation) (1) gave a presentation to feedback their view on the GREEN Statement (The Statement for Global Research Ethics Norm and Meaningful Engagement) (2, 3) and had a dialogue with a Japanese group of patients and the public, the Bioethics Working Group of the Japanese Institute for Public Engagement (Ji4pe) (4), during a small online meeting held on 4 February 2026. This Japanese group published the "Patient Public Declaration of Research Ethics" in 2024 (5) which is one of the important bases of the GREEN Statement, where members of EUPATI and Ji4pe also joined as co-authors. The Ji4pe Bioethics WG planned and hosted this dialogue with EUPATI to listen to their activities and views on the GREEN Statement.

EUPATI, launched as a public-private initiative in 2012 under the Innovative Medicines Initiative (IMI) of the European Commission, aimed to enhance patient understanding and involvement in medicines research and development (R&D). The multistakeholder consortium created educational materials, launched training courses for 'patient experts' (EUPATI Fellows), and empowered them to advise industry and academia. Later hosted by the European Patients' Forum (2017-2020), EUPATI operated as an educational programme.
"PharmaTrain" is an international quality-assured educational programme for both experts and patients/the public. EUPATI and PharmaTrain are separate entities with different missions that both originated within the Innovative Medicines Initiative (IMI) framework and share a common broader goal of advancing education related to medicines R&D.

A Japanese group is also learning under the educational programme provided by Ji4pe, which was established in 2020 by Dr Kyoko Imamrua, past President of both IFAPP (2018-2020) and JAPhMed (2009-2015). During the same year of the foundation of Ji4pe, this group voluntarily started activities as a bioethics working group in order to express their opinions on various topics of medical ethics while learning the basics of drug development in accordance with the PharmaTrain Syllabus (6) and the competencies required to be a member of an ethics committee.

What is the GREEN Statement?

The GREEN Statement was issued in September 2025 (2,3), originating from activities to bring public opinions to the World Medical Association (WMA)'s 2024 revision of the Declaration of Helsinki (DoH) (7). It forms the global efforts seeking the highest research ethics norm and requested international organisations such as the WMA, WHO (8) and UNESCO (9) as parts of the United Nations, and CIOMS (10) to incorporate their opinions in the GREEN Statement in future revisions of these research ethics standards (2, 3).

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The GREEN Statement also clarified the essential elements required for meaningful engagement in the research process of patients, research participants, the public, and relevant communities. Nearly 100 co-authors and endorsers, including members of EUPATI and Ji4pe, from around the world have participated in the GREEN Statement. The organisers of the GREEN Statement comprise five individuals: Varvara Baroutsou, Immediate Past President IFAPP, Kotone Matsuyama, President-elect IFAPP, Chieko Kurihara, IFAPP member, Dirceu Greco, Brazilian professor of infectious diseases and bioethics, and Takeo Saio, Japanese psychiatrist/internist, who participated in the aforementioned online conference. The GREEN Statement was developed based on the "Helsinki Statement" (11) (with more than 100 global endorsements), which highlighted improvements and challenges for the 2024 DoH. It was also based on the "Patient and Public Declaration of Research Ethics" (5), developed by the Bioethics WG of Ji4pe.

EUPATI's view and the next step

EUPATI's view on the GREEN Statement was as follows: Ji4pe members asked many meaningful questions about the European situation of learning about and engaging in the research and medicines development process. EUPATI introduced their organisation and activities and provided insightful answers to Japanese participants. The next meeting, scheduled for 6 April 2026, will see the two groups exchange views and opinions on data-driven research.

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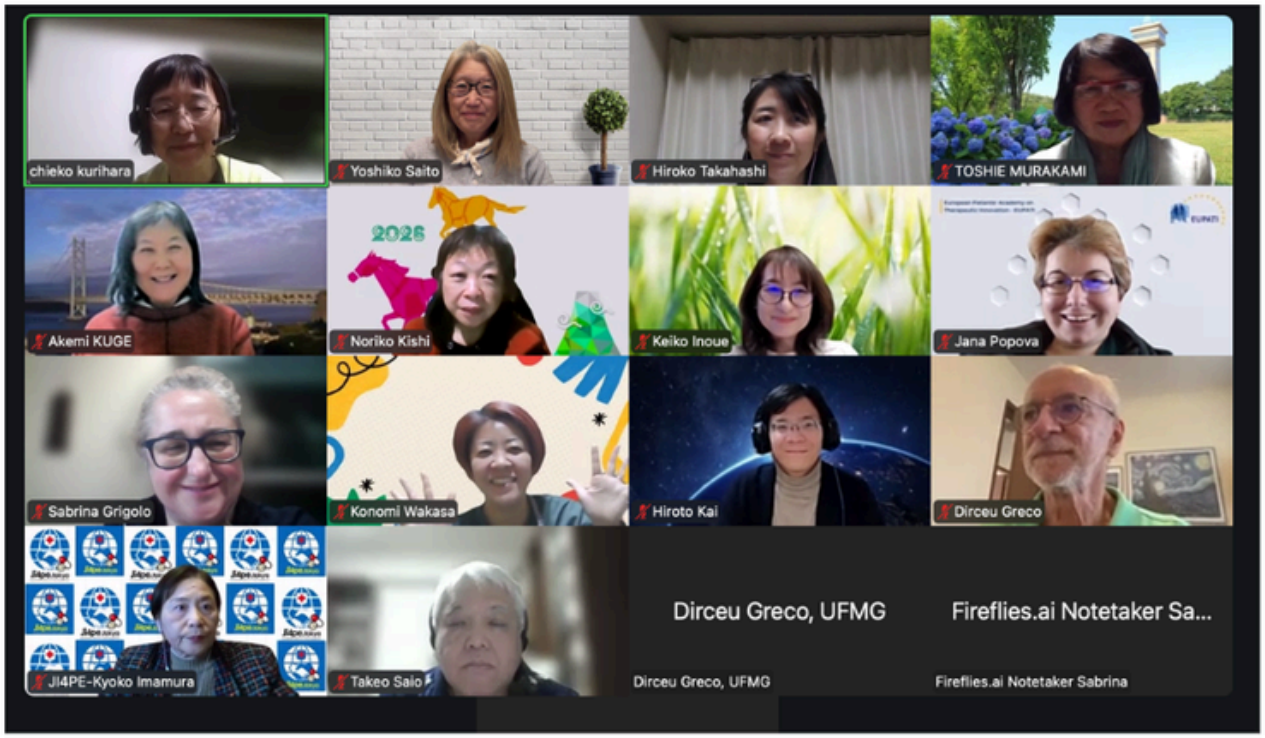
- The GREEN Statement enforces patient involvement by calling for patient and public participation in ethics committees, research governance, and oversight structures.
- The GREEN Statement reinforces EUPATI's advocacy for early and continuous involvement, ensuring patient perspectives shape research priorities, study design, and benefit-sharing.
- Both GREEN and EUPATI emphasise diversity, inclusivity, and equity, addressing structural barriers that limit participation of underrepresented patient communities.
- Alignment between GREEN and EUPATI institutionalises patient involvement as a standard ethical requirement, not an optional "good practice".



Snapshot of the online meeting held on 4 February 2026
EUPATI: Sabrina Grigolo, Jana Popova
Ji4pe Bioethics WG: Chieko Kurihara, Yoshiko Saito, Hiroko Takahashi, Toshie Murakami, Akemi Kuge, Noriko Kishi, Keiko Inoue, Konomi Wakasa, Hiroto Kai, Kyoko Imamura
GREEN Statement Organisers: Chieko Kurihara, Dirceu Greco, Takeo Saio

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References:

(1) EUPATI
(2) GREEN Statement Initiative. The Statement for Global Research Ethics Norm and Meaningful Engagement: GREEN Statement. Clinical Evaluation. 2025; 53(2).
(3) Kurihara C, Matsuyama K, Baroutsou V, Saio T, Greco D. GREEN Statement as the result of global discussions: Towards the Highest Ethical Standard of Research Ethics. IFAPP TODAY. 2025; No. 58: 1-3.
(4) Ji4pe: Japanese Institute for Public Engagement.
(5) Kurihara C, Saito Y, Kai H, Funabashi Y, Inoue K, Kishi N, Kuge A, Murakami T. Suzuki K, Takahashi H, Uchida E, Imamura K. Patient Public Declaration of Research Ethics (1st edition): Research ethics of the people, by the people, for the people—Expanding the impact of the 2024 revision of the Declaration of Helsinki. Clin Eval. 2024; 52(3): W28-39.
(6) PharmaTrain Syllabus. https://pharmatrain.eu/pharmatrain-syllabus
(7) The World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. First adopted in 1964, last amended in 2024. https://www.wma.net/policies-post/wma-declaration-of-helsinki/
(8) World Health Organization.
(9) United Nations Educational, Scientific and Cultural Organization.
(10) Council for International Organizations of Medical Sciences.
(11) Helsinki Statement Stakeholders. Helsinki Statement 2024. Clin Eval. 52(3): http://cont.o.oo7.jp/52pop/HelsinkiStatement_18Oct24_final.pdf

Authors:

Sabrina Grigolo, Jana Popova, EUPATI
Chieko Kurihara, Specially-appointed Professor, Kanagawa Dental University, Editor-in-Chief, Clinical Evaluation, Member of Bioethics Working Group of Ji4pe, Japan

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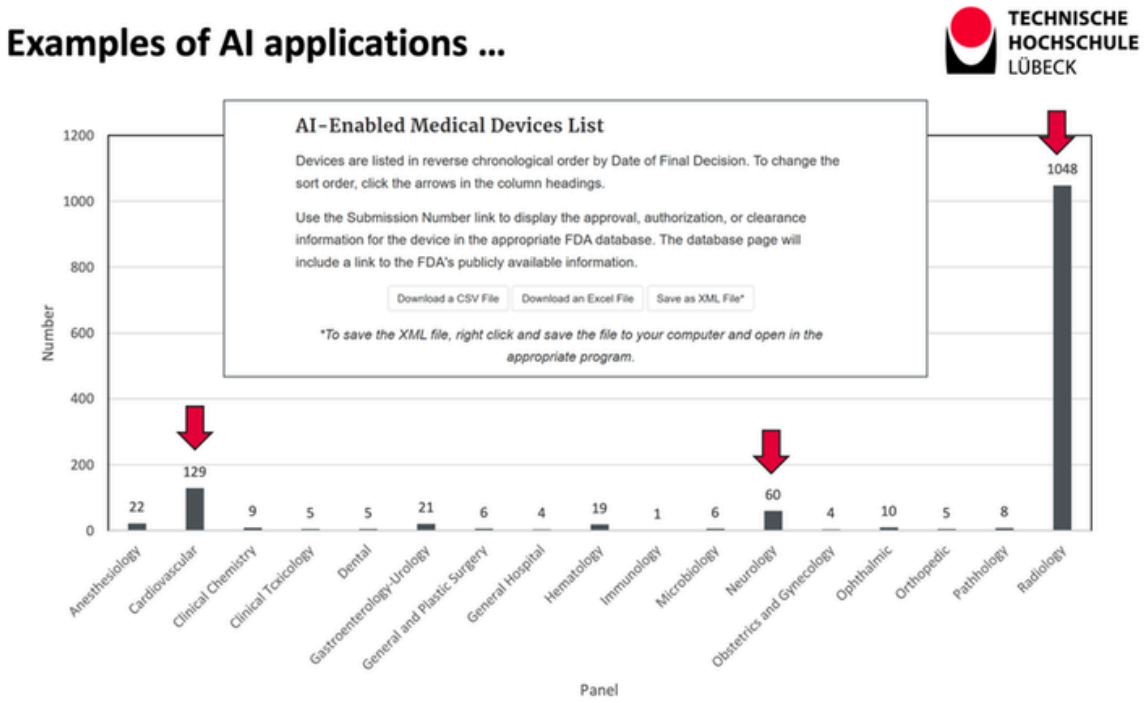
Summary of the IFAPP Virtual Workshop of 04 February 2026

Opportunities and Challenges in Implementing the European Artificial Intelligence (AI) Regulation: Overview of Content and Status of Implementation from a Regulatory Perspective

Speaker:
Professor Folker Spitzenberger, PhD, M.D.R.A.
Department of Applied Natural Sciences
Centre for Regulatory Affairs in Biomedical Sciences - CRABS
Technische Hochschule Lübeck University of Applied Sciences
Fraunhofer Einrichtung für Individualisierte Medizintechnik - IMTE

The presentation gave a reference to the US FDA database of approved artificial intelligence/machine learning-based medical devices.



[Source: **U.S. FDA – Database of Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices in the USA** (Current as of 31.01.2026]

A reference to examples of AI applications in individual phases of drug development were then given.

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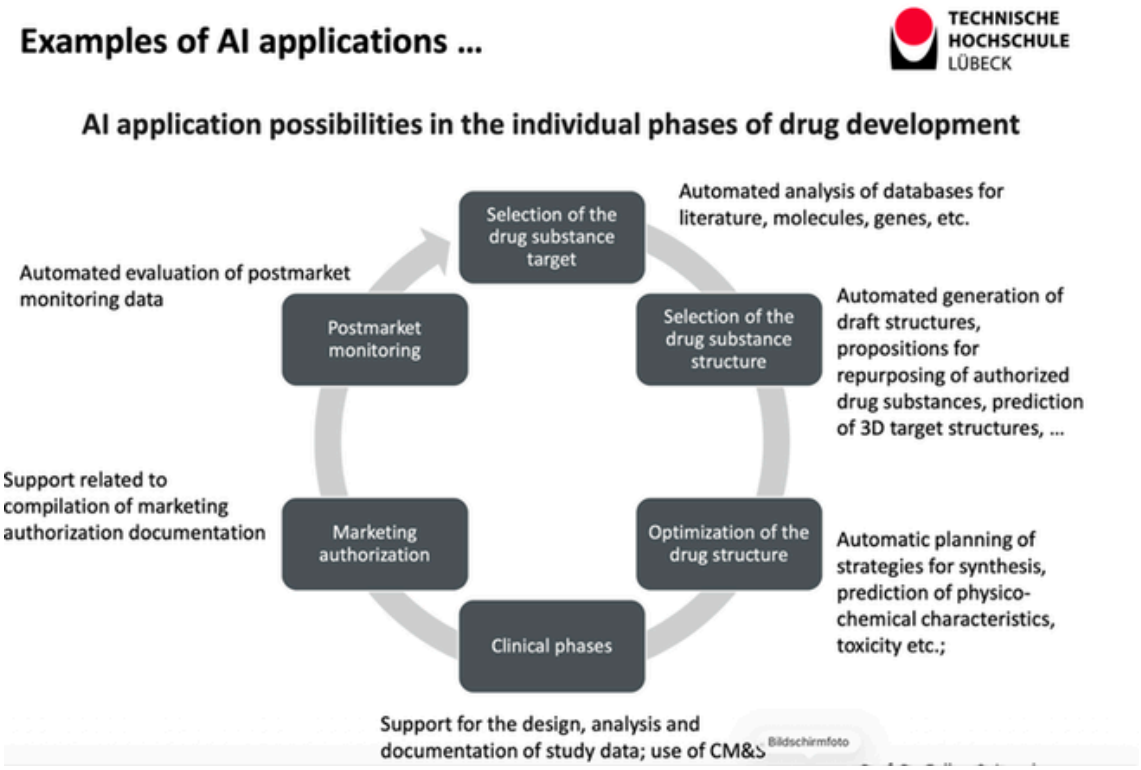
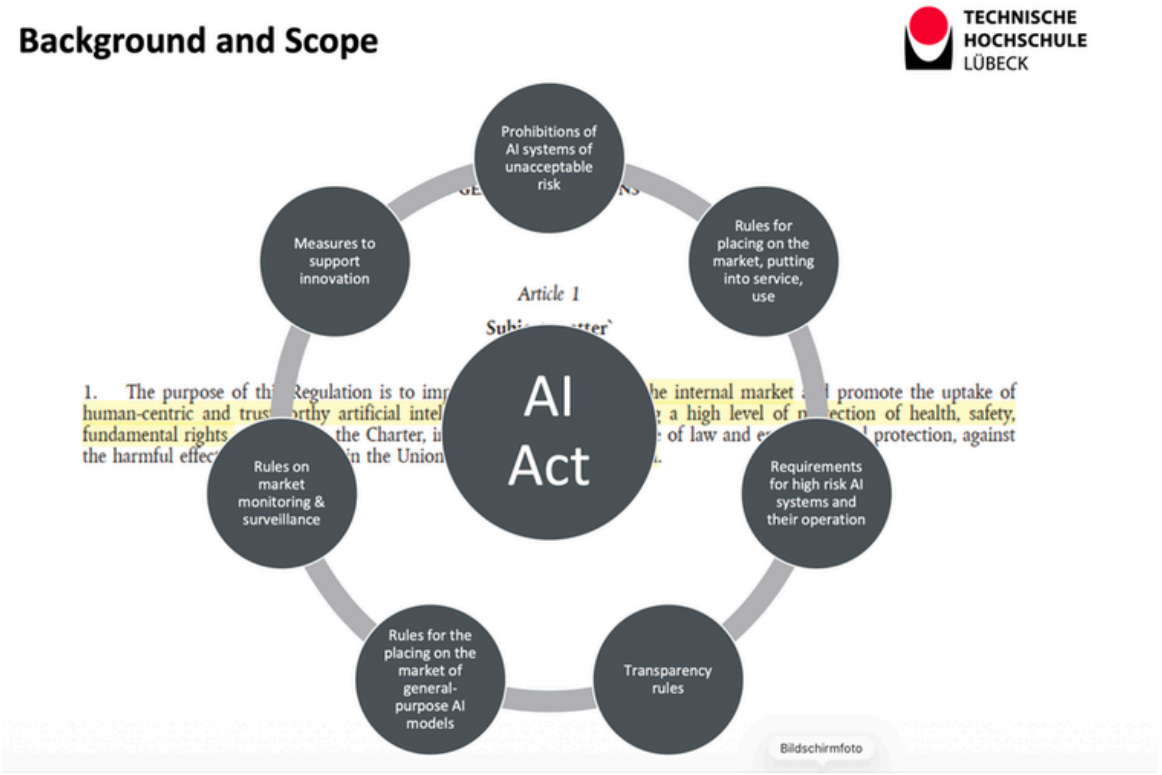


The links to the EU AI ACT were presented.



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Then detailed information regarding the content of the EU AI Act was provided

Background and Scope

TECHNISCHE HOCHSCHULE LÜBECK

Addressees:

Article 2

Scope

1. This Regulation applies to:

(a) providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;

(b) deployers of AI systems that have their place of establishment or are located within the Union;

(c) providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union;

(d) importers and distributors of AI systems;

(e) product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;

(f) authorised representatives of providers, which are not established in the Union;

(g) affected persons that are located in the Union.

„operators"

Definitions/glossary were explained.

Background and Scope

TECHNISCHE HOCHSCHULE LÜBECK

Addressees:

'provider' means a ... body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge

'deployer' means a body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity

'distributor' means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market;

'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

'importer' means a natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established in a third country;

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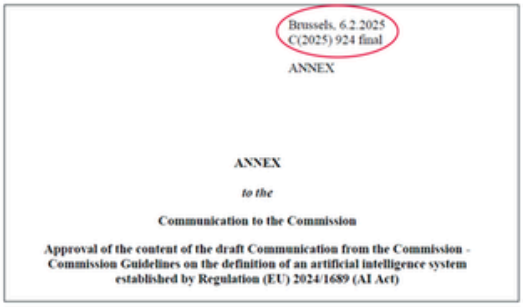
Background and Scope

TECHNISCHE HOCHSCHULE LÜBECK

Definition „AI system“

'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;


Brussels, 6.2.2025
C(2025) 924 final

ANNEX

ANNEX

to the

Communication to the Commission

Approval of the content of the draft Communication from the Commission - Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)


EUROPEAN COMMISSION

Brussels, 29.7.2025
C(2025) 5053 final

COMMUNICATION FROM THE COMMISSION

Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)

https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application

Bildschirmfoto

The focus lay on the risk-based approach of the EU AI Act.

Chapter No.	Title	Title Content
I	GENERAL PROVISIONS SCOPE AND DEFINITIONS	Scope of application, definitions.
II	PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	List of prohibited AI
III	HIGH-RISK AI SYSTEMS	Classification rules for high-risk AI systems, horizontal obligations on providers for conformity assessment
IV	TRANSPARENCY OBLIGATIONS FOR PROVIDERS AND DEPLOYERS OF CERTAIN AI SYSTEMS	Transparency obligations for systems that (i) interact with humans, (ii) are used to detect emotions or determine association with (social) categories based on biometric data, or (iii) generate or manipulate content ('deep fakes')
V	GENERAL-PURPOSE AI MODELS	Classification rules for providers of general-purpose AI models; obligations for providers of general-purpose AI models
VI	MEASURES IN SUPPORT OF INNOVATION	National AI regulatory sandboxes to test innovations on the basis of a testing plan agreed with the competent authorities
VII	GOVERNANCE AND IMPLEMENTATION	Governance systems at Union and national level: European Artificial Intelligence Board and national supervisory authorities
VIII	EU DATABASE FOR HIGH-RISK AI SYSTEMS	EU-wide database for stand-alone high-risk AI systems listed in Annex III
IX	POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	monitoring and reporting obligations for providers of AI systems; market surveillance according to Regulation (EU) 2019/1020
X	CODES OF CONDUCT and GUIDELINES	framework for the creation of codes of conduct to be voluntarily followed by providers of non-high-risk AI systems
XI	DELEGATION OF POWER AND COMMITTEE PROCEDURE	rules for the exercise of delegation and implementing powers
XII	Penalties	
XIII	FINAL PROVISIONS	Rules for update, reports and transition periods for applicability

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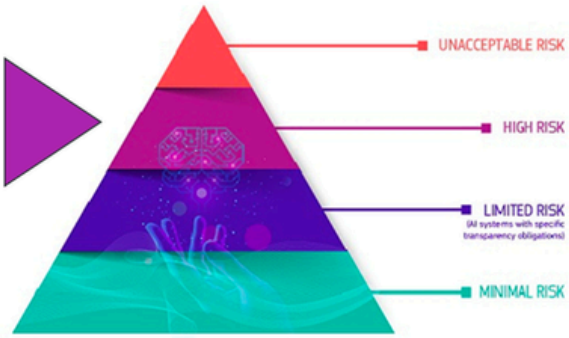
AI Act – Risk categorization

TECHNISCHE HOCHSCHULE LÜBECK

(1) … that **AI system shall be considered to be high-risk where both** of the following **conditions are fulfilled**:
(a) the **AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by** the Union harmonisation **legislation listed in Annex I**;
(b) the **product** whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, **is required to undergo a third-party conformity assessment**, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I. …
(2) **AI systems referred to in Annex III shall be considered to be high-risk** …

AI Act, Article 6 (1), (2), in extracts



Source: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

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AI Act – Risk categorization

TECHNISCHE HOCHSCHULE LÜBECK

https://digital-strategy.ec.europa.eu/en/faqs/navigating-

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Bringing the challenges in line with the CE* marking process…

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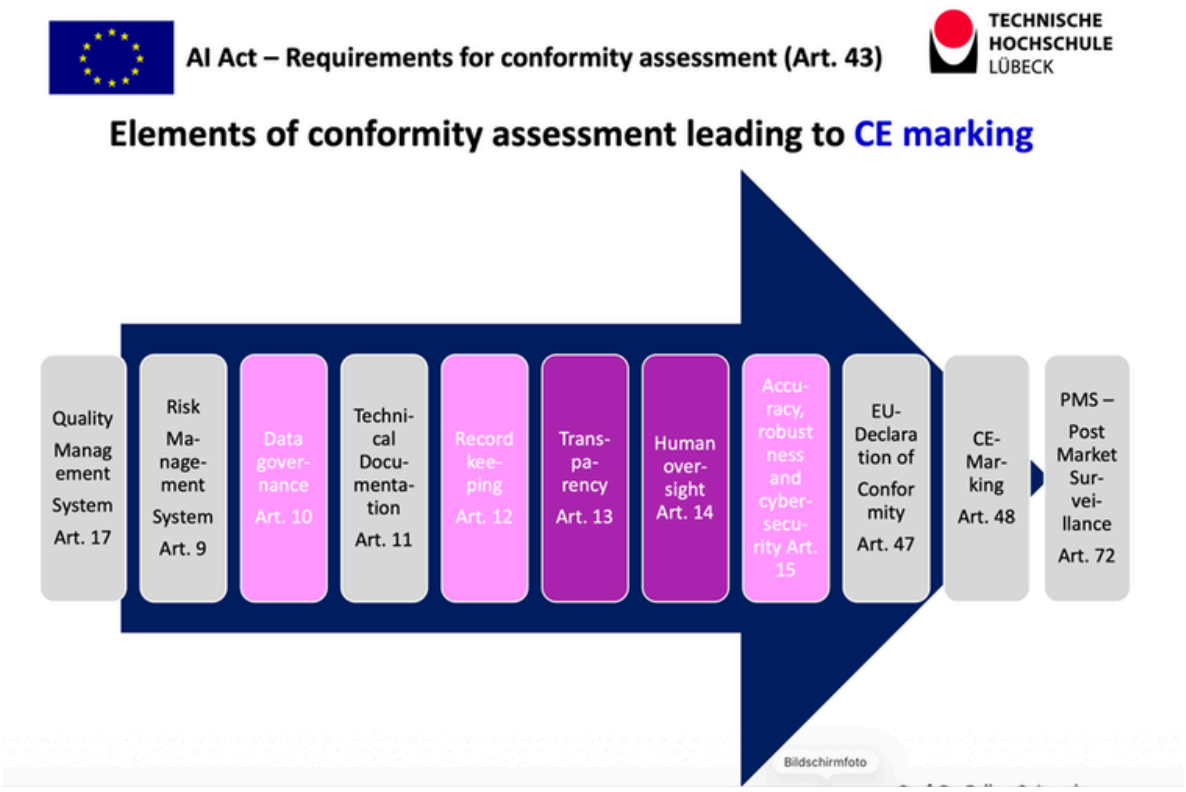
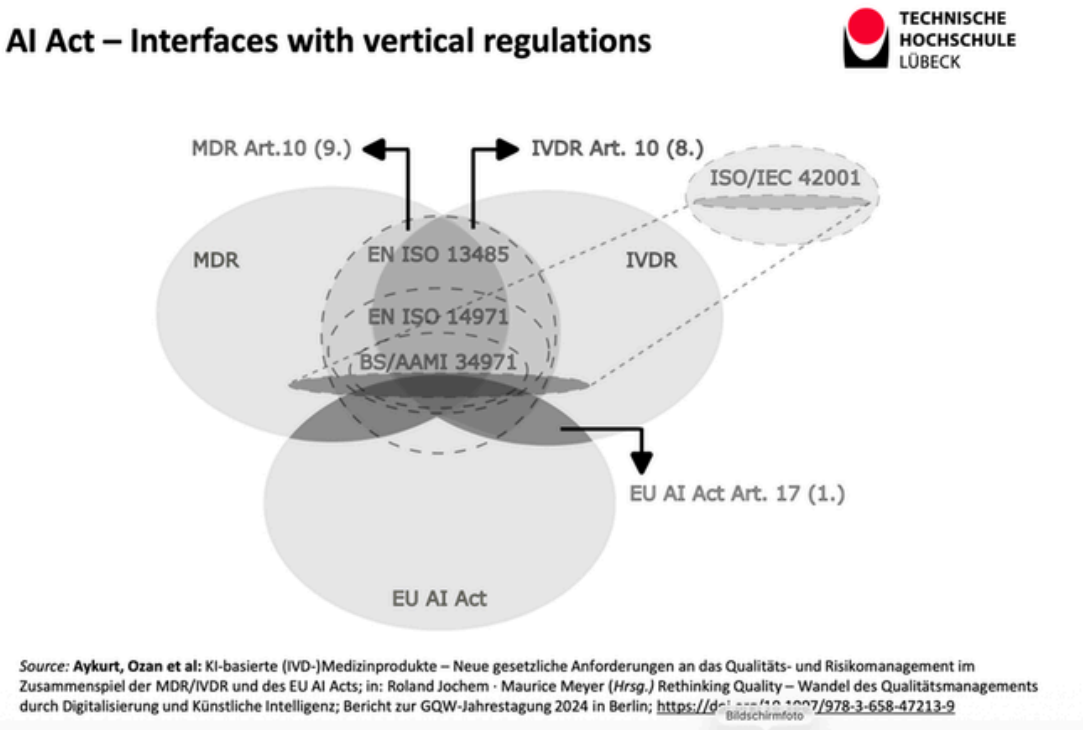


*CE: Conformité Européene Mark (CE Mark).

... and linking it to other requirements and obligations:



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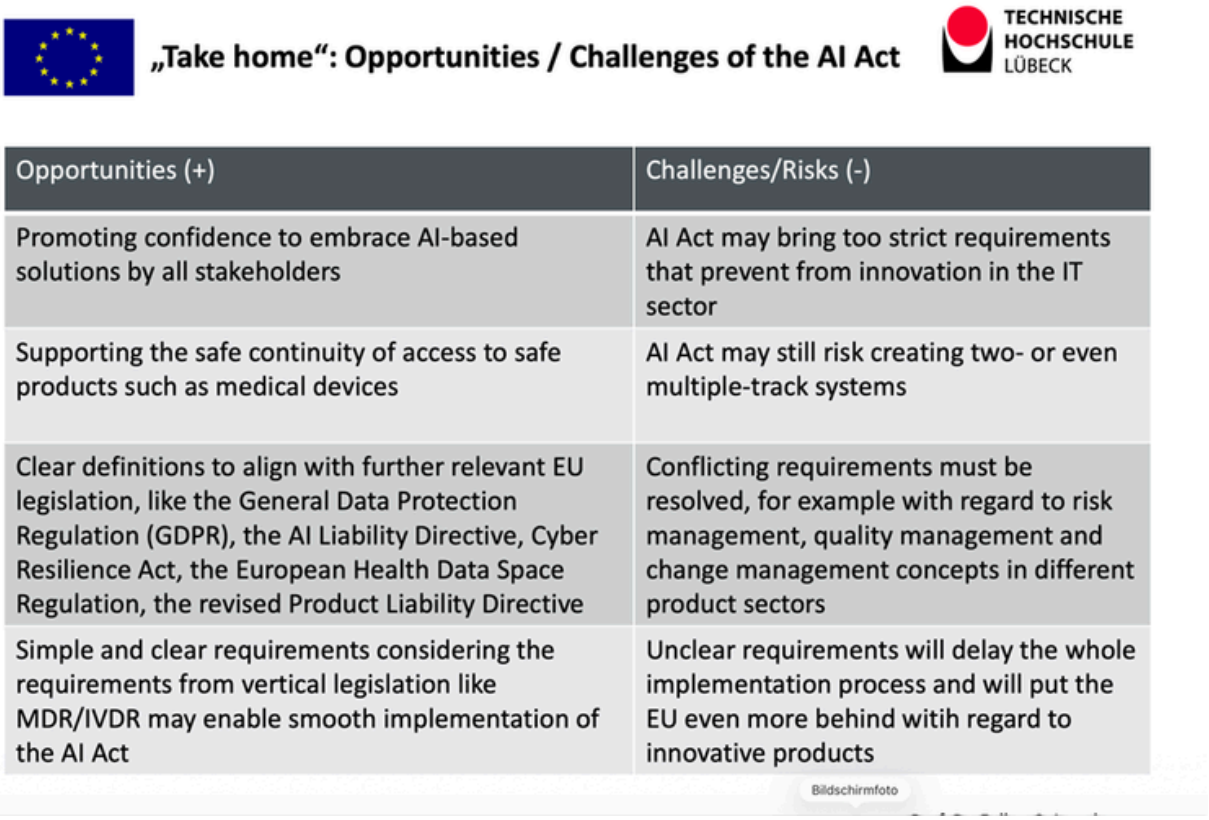
Take home messages:



The full set of slides and the video recording can be found here:
https://www. youtube.com/watch?v=xB5zhlYmF5A, resp. here:
https://www.youtube.com/watch?v=xB5zhlYmF5A/Folker Spitzenberger Webinar on EU AI Regulations

Author:
Birka Lehmann, MD PhD, Chair of IFAPP's Education and Certification Working Group (ECWG), Senior Expert Drug Regulatory Affairs

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Summary of the IFAPP Virtual Workshop of 19 February 2026

EU IVDR implementation - State of Play and Challenges

Speaker:
Todor Darakchiev, M. Pharm., Head of Division „Medical Devices“, Dept. Market Surveillance and Inspections, Bulgarian Drug Agency

Regulation (EU) 2017/746 IVDR (1)) represents the most significant reform in the regulation of in-vitro diagnostic medical devices in the European Union over the past decades. With its application from 26 May 2022, Directive 98/79/EC was replaced, and a new, considerably stricter and more centralised regulatory framework was introduced.

The main objective of this Regulation is to enhance the safety, traceability, and quality of diagnostic devices, which play a crucial role in clinical decision-making and public health.

The IVDR fundamentally changed the regulatory philosophy, shifting from a more liberal model with a high degree of self-declaration to a system with strengthened oversight, stricter requirements for technical documentation, clinical evidence, and increased involvement of notified bodies.

The presentation started with the information where to find important information:

The Regulations on **Medical Devices** (Regulation (EU) 2017/745) and on **In Vitro Diagnostic Devices** (Regulation (EU) 2017/746) changed the European legal framework for medical devices, introducing new responsibilities for EMA and national competent authorities in the assessment of certain categories of medical device.

- The Medical Devices Regulation applies since 26 May 2021. Manufacturers must comply with the Regulation when placing new medical devices on the market. It repeals Directive 93/42/EEC on medical devices and the Directive 90/385/EEC on active implantable medical devices.
- The In Vitro Diagnostic Devices Regulation applies since 26 May 2022. It repeals Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

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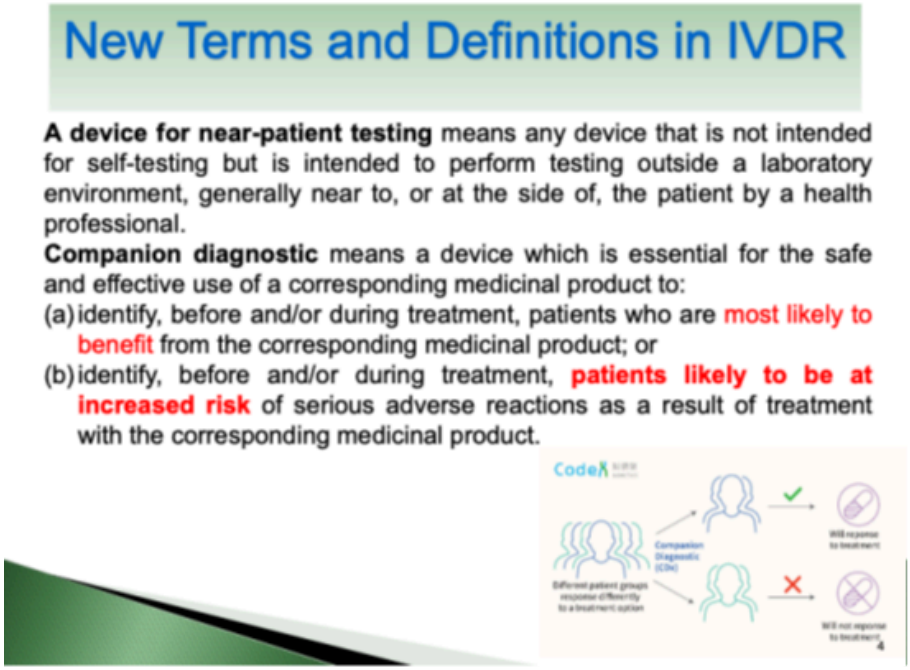
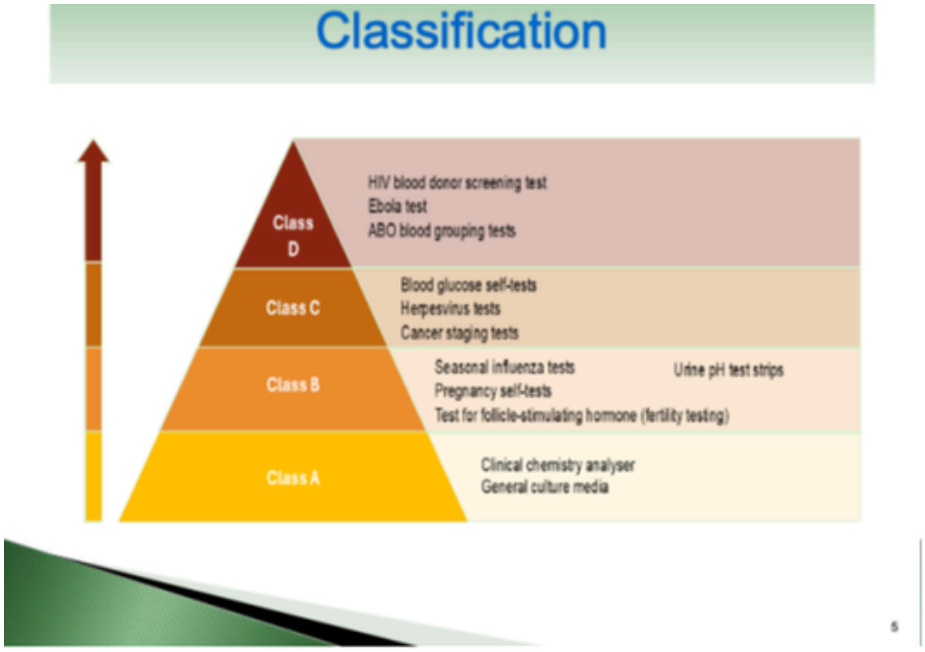
Definitions/glossary were explained:



Information was presented with regard to the new classification in respect to risk:



A significant proportion of devices were reclassified into higher risk classes, leading to a sharp increase in the scope of mandatory conformity assessment by notified bodies. This substantially increases the administrative burden, costs, and time to market.

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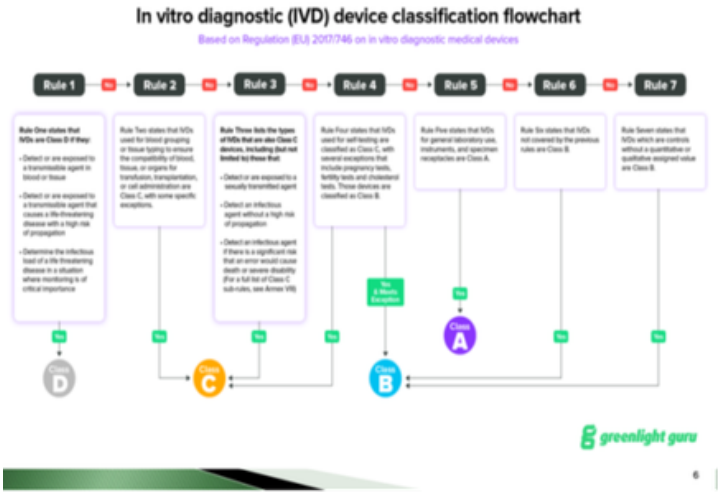
Particularly sensitive are Class D devices, for which an additional layer of control was introduced through the European Union Reference Laboratories (EURLs). These bodies verify performance characteristics and may participate in batch testing of high-risk diagnostic products. The aim is to ensure maximum reliability for tests related to serious infectious diseases and other critical conditions

The information which IVD has to follow which rule to be placed on the EU Market were provided in excellent well-structured tables:



Transitional Provisions (IVDR, Art. 110)

IVDR classification	Extended deadline
Class A sterile	31 December 2029
Class B	31 December 2029
Class C	31 December 2028
Class D	31 December 2027

Transitional provisions (IVDR, Art. 110)

Requirement	Applicable deadline
The device continues to comply with the previous Directives.	Ongoing requirement
The device does not undergo a significant change to its design and intended purpose.	Ongoing requirement
The device does not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.	Ongoing requirement
The manufacturer has put in place a quality management system (QMS) in accordance with Article 10(8) of the IVDR.	26 May 2025
The manufacturer or authorised representative has lodged an application for IVDR certification with a notified body.	Class D: 26 May 2025 Class C: 26 May 2026 Class B and A sterile IVDs: 26 May 2027
The manufacturer has signed a written agreement with a notified body.	Class D: 26 September 2025 Class C: 26 September 2026 Class B and A sterile IVDs: 26 September 2027

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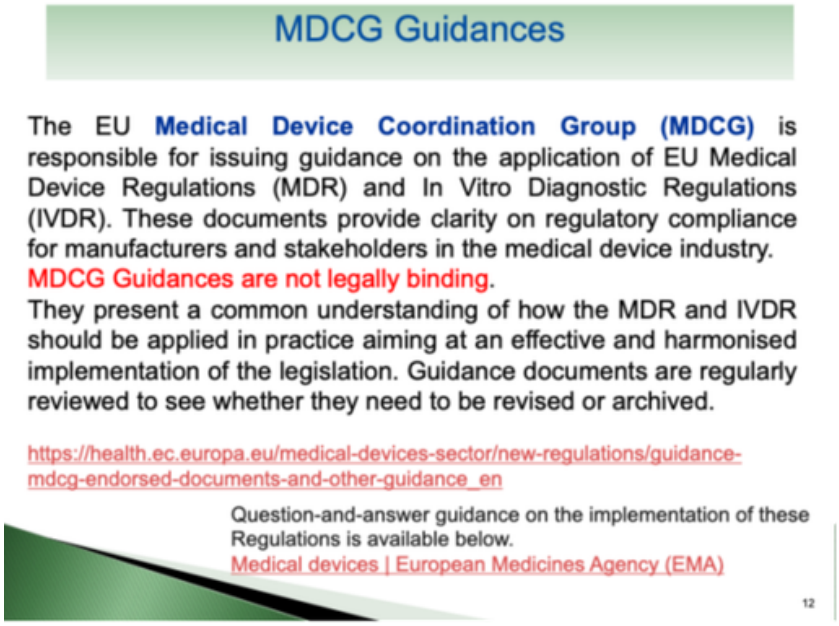
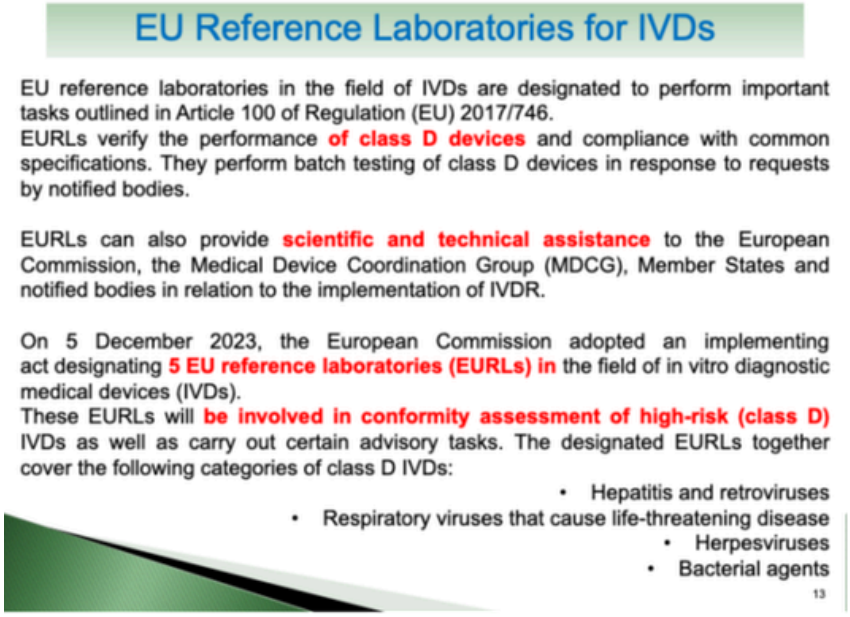
There is still a lot of guidance needed for the implementation of the IVD-Regulation, e.g. the



And more IVD Laboratories are needed to for an adequate implementation of the Regulation:



The European Database on Medical Devices (EUDAMED) update provides the following information:

The first four modules of the EUDAMED database (Actors (2), UDI (3), Notified Bodies and Certificates, Market Surveillance) are completely functional and have to be used mandatorily from 28 May 2026. A Vigilance module is expected to come in mandatary use in Q2 2027. The clinical investigation and performance study module remains under development without a date for mandatory use so far.

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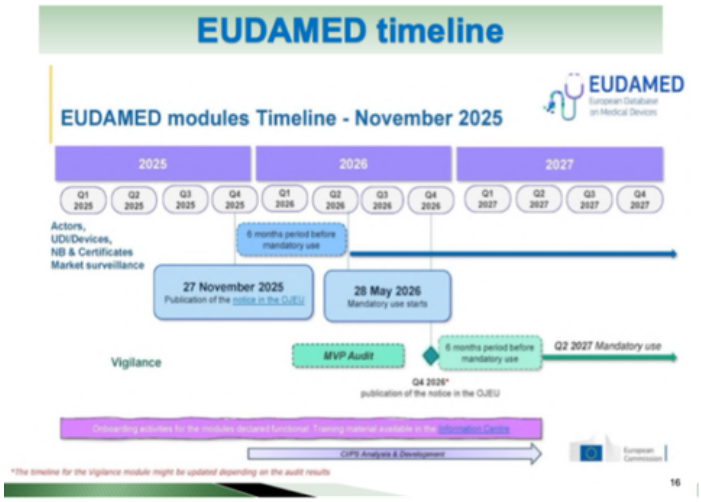

Other topics of relevance were touched:

Supply Chain
In parallel, the Regulation introduced new obligations related to supply chain management. Subsequent amendments established a requirement for manufacturers to notify competent authorities in the event of a risk of serious supply disruption that could endanger patients or public health. This element demonstrates that the IVDR approaches regulation not only from a compliance perspective but also as an instrument for market stability.

Limited Number of Notified Bodies
Despite the clear objective of enhancing safety, the practical implementation of the IVDR has faced significant challenges. The limited number of notified bodies and the lengthy designation process led to delays in certification and a risk of shortages of certain diagnostic devices. This necessitated extensions of the transitional periods and the removal of the so-called “sell-off” date to prevent the sudden withdrawal of products from the market.

All devices that were placed on the market before the introduction of the new deadlines and during the transitional periods may continue to be sold.
At the same time, the European Commission has taken steps toward simplification and targeted revision of the regulatory framework in order to reduce administrative burden and maintain the competitiveness of the European medical device sector.

Breakthrough Devices
Mechanisms for accelerated assessment of innovative and “breakthrough” devices have also been introduced, reflecting an effort to balance strict regulatory control with the encouragement of innovation.

Take-home messages
Overall, the IVDR represents a systemic transformation of the European market for in-vitro diagnostic medical devices. It raises standards for safety and transparency, while simultaneously creating significant organisational and economic challenges for manufacturers, notified bodies, and national competent authorities.

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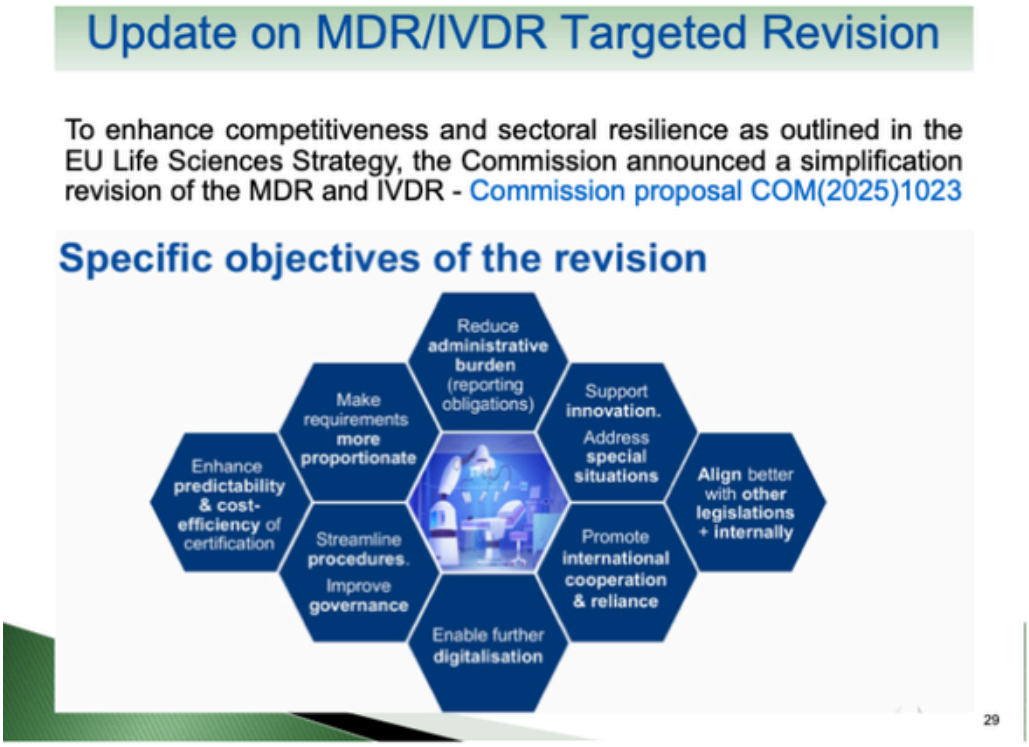
The current stage can be described as a phase of adaptation and structural stabilisation, in which regulatory stringency is gradually being combined with flexibility measures aimed at ensuring the sustainability and accessibility of diagnostic technologies within the European Union.



The slides are available for IFAPP members upon request. Send an email to the Board Secretary anna.jurczynska@ifapp.org and indicate your membership.
A recording of the webinar is not available due to technical issues.

Abbreviations/Explanations:
1) IVDR: In-vitro Diagnostic Regulation
2) Actors: All economic operators
3) UDI: Unique Device Identification

Authors:
Birka Lehmann, MD PhD, Chair of IFAPP's Education and Certification Working Group (ECWG), Senior Expert Drug Regulatory Affairs
Prof. Dr Tatyana Benisheva, Medical University, Sofia- Bulgaria - Faculty of Public Health, Member of IFAPP's ECWG

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Strategies for Successfully Switching Roles in Pharma

Summary of the Webinar "Career Pivots: Switching Roles within Pharma (and How to Do it)" organised by the YPWG* on January 28, 2026

Many early-career professionals enter pharma assuming they must choose one path and stay on it, believing that their initial decision will define their entire trajectory. However, this is a misconception; few careers in the pharmaceutical industry follow a straight line. Instead, most professionals find that their journeys involve periods of exploration, growth, and change.

In our recent IFAPP Young Professionals webinar, "Career Pivots: Switching Roles within Pharma (and How to Do It)", we explored how professionals can approach transitions strategically rather than reactively.
Our guest speaker, Nikos Tsokanas, Managing Director at Lean Pharma Services, shared his own career journey across roles and functions. His story highlighted a key message: career pivots rarely happen by chance. They require intention, preparation, and self-awareness.

As the industry evolves and new opportunities emerge, individuals often pivot between roles, departments, or specialties, discovering new interests and expanding their skill sets along the way. This flexibility is not only possible but encouraged as it allows professionals to build a diverse portfolio of experiences and adapt to the shifting demands of the sector. Recognising that career paths are rarely linear opens the door to intentional development and strategic choices, rather than feeling confined to a single, predetermined track.

Transitioning to a new role within the pharmaceutical industry requires more than simply updating your resume. It is essential to recognise which skills can be transferred to a different position, pinpoint areas where your abilities may be lacking, and actively develop the competencies necessary for your desired role. Often, this preparation needs to happen before opportunities are formally available. By planning in advance, professionals can approach new roles confidently, rather than feeling pressured to make sudden decisions.
During the discussion, Nikos shared concrete advice for professionals considering a career pivot:

1. Clarify what truly attracts you to the new role
Before making a move, reflect on what you genuinely enjoy; the responsibilities, the problem-solving aspect, the level of ownership, or the strategic impact. A clear motivation leads to a more sustainable transition.

2. Start building skills now
Look at your current position and ask: how can I already develop the competencies needed for the next role? Volunteer for cross-functional projects, take on stretch assignments, or deepen expertise in adjacent areas.

3. Use your network intentionally
Speak with friends and colleagues. Let people know what you are exploring. Many opportunities arise through conversations and recommendations rather than formal applications.

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4. Reach out directly
If a job posting interests you, contact the hiring manager. Ask what profile they are truly looking for and how you could strengthen your candidacy. This initiative demonstrates motivation and provides valuable insight.

5. Prepare before you pivot
Career shifts are strongest when preparation precedes opportunity.

For those early in their careers, the lesson is particularly important: do not wait until circumstances force you to change. Take the initiative to explore the various possibilities within the pharma sector, consider where you want to develop, and start preparing now for the position you aspire to achieve in the future.

Ultimately, a career in pharma is not a linear journey. It is made up of a series of intentional steps, forming a portfolio of experiences that reflect thoughtful progression and growth.

A career is not a single track; it is a portfolio of deliberate steps.

And now we are pleased to invite you to our next webinar of the "Grow with the Experts" series on **17 March 2026, 12:00–12:45 CET: "Parenthood in Pharma: Strategies for Thriving before, during and after Leave."** In this interactive session, **Raoul Giger**, Pricing & Market Access Manager at Sanofi Switzerland, will share practical insights on navigating career progression alongside parenthood. From planning a smooth transition before leaving, to maintaining visibility during absence, and re-entering the workplace with confidence, the discussion will focus on realistic strategies that support both professional growth and personal priorities. Join us for an open and solution-oriented conversation on how to build a sustainable career in pharma at every stage of life.

Here is the link to register for the webinar:
https://us02web.zoom.us/webinar/register/WN_QmyYFZ10R3uEgnMki5W7sA

Author:
Kateryna Uspenska
Chair of the Young Professionals Working Group (*YPWG), IFAPP
Senior Clinical Project Manager
Gouya Insights, Austria

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Click here to register for this webinar

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Introducing the Online Global Medicines Development MSc at King's College London

Medicines development is a global business. A trial designed in London may recruit patients in India, manufacture the product in the USA, and file for approval across three continents. If you work in pharma, biotech, or clinical research, or you want to, you need to understand how all those pieces fit together.

The online MSc in Global Medicines Development at King's College London covers the full journey of a medicine: early discovery, non-clinical testing, clinical trials, regulation, safety and pharmacovigilance, and commercialisation. It is built on the PharmaTrain Syllabus V3.0, which sets the international standard for how medicines development is taught, and it is delivered by academics, industry experts, and regulatory specialists.

The programme is designed for working professionals. You do not need to stop working to study. It runs part-time, fully online, with intakes in January, May, and September. Our students come from across the world; the UK and Europe, Africa and the Middle East, North and South America, South and Southeast Asia, and this international mix is one of the programme's strengths. You will work in teams across time zones and different professional backgrounds, because that is how the industry actually works.

Each module uses real-world case studies. You will work through scenarios in clinical trial management, non-clinical development, regulatory strategy, safety, medical affairs, and commercialisation. The assessments are designed to test professional judgement, not a student's memory.

By the end, you'll understand how medicines get from the lab to patients, and you'll be better equipped to lead those programmes.

The next intake starts on **18 May 2026**. Applications close **20 April 2026**.
For more information or to apply, please visit the programme page: https://eu1.hubs.ly/H0nJ4d_0

Authors:

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King's College London.

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IFAPP Free Webinar: Ethics in Data-Driven Research (part 3): Opinions from Patients and the Public - 23 March 2026

Click here to register for this webinar.

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IFAPP Free Webinar: New Provisions in the Pharma Legislation: Will They Solve the Future Challenges Concerning Pharmaceuticals - 15 April 2026

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Speaker
Prof. Dr Christa Wirthumer-Hoche
Former Head of the Austrian Agency for Medicines and Medical Devices and Chair of the EMA (1) Management Board

Content
The general pharmaceutical legislation adopted on 11 December 2025 represents a major modernisation of EU pharmaceutical law addressing several critical issues such as access, regulatory efficiency, innovation incentives and supply security.

Individual provisions are discussed and their impact on healthcare supply with medicines is outlined. An overview will be presented.

However, this general pharmaceutical legislation alone cannot solve all the challenges in the pharmaceutical sector; supplementary legislation is needed, such as the Critical Medicines Act, European Health Data Space and AI (2) tools. The interaction between these regulations is also examined.

Register in advance for this webinar webinar!

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

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

CV of Prof. Dr Christa Wirthumer-Hoche

Prof. Dipl. Ing. Dr Christa Wirthumer-Hoche studied biochemistry and graduated at the Technical University, Vienna, in 1981, and wrote her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. She joined the Austrian National Institute for Quality Control of Drugs, afterwards the Austrian Federal Ministry of Health and Women and from 2006 to 2023 the Austrian Medicines and Medical Device Agency, always in a leading role. In October 2013, she was appointed Head of the Austrian Agency for Medicines and Medical Devices.

At a European level, from 1994 to 2023, Prof. Wirthumer-Hoche has been involved in different European committees and working groups and, in 2016, she was the first woman to be elected Chair of the EMA's Management Board and was re-elected for a second term in 2019. Also at international level, within ICH (3) and ICMRA (4) she was an active member.

Since 1 April 2023 Prof. Wirthumer-Hoche has been retired but is still active as a lecturer on the subject "regulatory affairs and cooperation of different stakeholders in Europe in the field of marketing authorisation and life cycle activities of medicinal products", at different universities. During the review of the general Pharma legislation, she was a consultant to the Ministry of Health of Austria. She was and is involved in EC (5) projects that support the establishment of national regulatory authorities in countries with less developed regulatory systems.

Abbreviations

1) EMA: European Medicines Agency
2) AI: Artificial Intelligence
3) ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
4) ICMRA: International coalition of Medicines Regulatory Authorities
5) EC: European Commission

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Free Webinar: "Are We Running out of Antimicrobials?", 26 May 2026, 12.00 noon CEST

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.

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.

Registration link: https://us02web.zoom.us/webinar/register/WN_IXVxIn2RQR2wL66dhK5WYA

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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09 March 2026 Online Publication of star.admin.ch – the Federal Government's Platform on the Topic of Antibiotic Resistance with Regard to the World AMR Awareness Week 2025

TOGETHER AGAINST ANTIMICROBIAL RESISTANCE

"The Swiss Society for Pharmaceutical Medicine (SGPM; https://sgpm.ch) devoted their 2025 Annual Symposium of Pharmaceutical Medicine on the occasion of their 30th anniversary (https://www./www.annual-meeting.ch) to the topic Antimicrobial Resistance (AMR) in collaboration with the European Center of Pharmaceutical Medicine (ECPM; https://ecpm.unibas.ch) and the Swiss Round Table on Antibiotics (https://roundtableantibiotics.ch/).

The congress with the title Racing against Resistance: The Future of Antimicrobials offered a unique selection of insightful presentations and was chaired (moderated) by Stephan Harbarth (University Hospital Geneva, HUG): from the impact of AMR on vulnerable patient groups via the monitoring of antibiotic treatment, possibilities for investors and innovative reimbursement (compensation) systems within the field of antibiotics, new (novel) approaches in clinical development and their regulatory challenges up to basic research and the Swiss strategy with reference to antibiotics resistance (StAR; https://www.star.admin.ch/en)."

Link: Summaries of more events during the WAAW 2025 are published on the Swiss FOPH (1) website: https://www.star.admin.ch/en/waaw-en#impressions

A summary of the event was published in the January edition of IFAPP TODAY:
https://ifapp.org/wp-content/uploads/2026/01/IFAPP_TODAY_60_January_2026.pdf

1) FOPH: Federal Office of Public Health

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IFAPP TODAY Editors Meet at the Grand Egyptian Museum

IFAPP TODAY editors Brigitte Franke-Bray and Yasmin Nagaty recently enjoyed a delightful day at the iconic new Grand Egyptian Museum (GEM). While Yasmin is based in Egypt, Brigitte's visit from Basel, Switzerland, created the perfect opportunity to connect in person, something that always brings a special kind of energy which virtual meetings cannot replicate.

Adding to the serendipity of the occasion, Assem el Baghdady, President of MEAPP, IFAPP's National Member Association of the Middle East, and also a member of IFAPP's Communication Working Group, happened to be in Cairo at the same time, creating an unexpected opportunity for a valuable in-person meeting.
Set against the breathtaking backdrop of one of the world's most remarkable cultural landmarks, the meeting was filled with genuine conversation, shared laughter, and the simple joy of being together in person.

Moments like these are a beautiful reminder that, beyond emails and screens, it is face-to-face connections that truly strengthen friendships and our sense of community.

With the compliments of the editors: Brigitte Franke-Bray and Yasmin Nagaty

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Free Webinars

- 17 March 2026 - Parenthood in Pharma: Strategies for Thriving Before, During & After Leave.
  Click here to register.
- 23 March 2026 - Ethics in Data-Driven Research (Part 3): Opinions from patients and the public.
  Click here to register.
- 15 April 2026 - New Provisions in the pharma legislation: will they solve the future challenges concerning pharmaceuticals.
  Click here to register.
- 26 May 2026 - Are We Running out of Antimicrobials?
  Click here to register.

THE FLAG

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