# IFAPP TODAY

The Global Pharmaceutical Medicine Journal

**INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE**

## THIS ISSUE:




## Introducing the New Chair of the IFAPP Young Professionals Working Group

By way of introduction, I am Joanne Ramsey the newly elected Chair of the IFAPP Young Professionals Working Group and therefore became a member of the IFAPP Board of Officers in December 2023. I have been Assistant Professor in Pharmaceutical Medicine and acted as coordinator of the course in Trinity College Dublin since 2019.

I am a qualified Biomedical Scientist following my studies at University of Ulster and working in the NHS hospital labs in Northern Ireland. In 2011, I obtained my PhD from Queen’s University Belfast studying pharma-cogenomics in haemato-oncology. Following completion of the PhD, I took up a biopharmaceutics research position in the Royal College of Surgeons in Ireland (RCSI) working on Advanced Therapy Medicinal Products and tissue regenerative medicine.

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Later, I became a pharmaceutics lecturer and principal investigator in RCSI and obtained a postgraduate qualification in Health Professions Education. It was in this work I found a joy in mentoring through supervision of MSc and PhD students and watching them achieve their success. This passion deepened in 2019 when I moved to Trinity to coordinate the Pharmaceutical Medicine course guiding students in their studies and research in the field.

Continuing professional development and furthering one's career is never a small undertaking but an important one, nonetheless. The continuous refresh of talent in Pharmaceutical Medicine is always exciting to see! Young professionals often bring new concepts to the field, challenge once consolidated thinking, and help us stay competitive and current in a rapidly changing world. The Young Professionals Working Group is vital to supporting this where young colleagues can engage through networking, learn from their peers, and grow professionally with support from those in an established mentoring capacity.

My vision as chair of the Working Group is to provide means in which young professionals can achieve their best career potential and that begins with understanding where they can/do fit in the field of Pharmaceutical Medicine. Here are ways in which I hope to achieve this vision:

- Develop engaging content to highlight career pathways for Young Professionals and foster new interest in a career in Pharmaceutical Medicine.
- Continue working with the Education and Certification Working Group to provide quality content on current knowledge in Pharmaceutical Medicine.
- Reach out and expand the awareness of the profession to those looking for an exciting new career challenge, utilising our social media channels to heighten IFAPP's presence.
- Align Young Professionals with mentors who can complement and invest in the successful journey of IFAPP's experts of the future.
- Shine a spotlight on our young IFAPP members highlighting their achievements, their contributions to IFAPP and where they wish to see themselves progress towards.

As a member of the IFAPP Education and Certification Working Group and the Communications Working Group and IFAPP delegate for the PharmaTrain Syllabus Revision Project, I will work to best represent and support the empowerment of our young professionals.

Through working with the members of the Young Professionals Working Group and bridging across to other working groups within IFAPP, my hope is that we can ensure a bright career for those in Pharmaceutical Medicine. Additionally, ensuring we have well-trained professionals working to safeguard Public Health and provide a better healthcare for all.

**Joanne M Ramsey PhD DPP PGCertHPE**
Assistant Professor in Pharmaceutical Medicine in Trinity College Dublin, University of Dublin

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## Introducing a New IFAPP Board Member: Robert Lins

Robert Lins was elected Chair of the IFAPP External Affairs Working Group (EAWG) and member of the IFAPP Board of Officers in December 2023. The working group is responsible for establishing and maintaining strategic partnerships with IFAPP's key stakeholders in Global Pharmaceutical Medicine, based on IFAPP's overall strategy and mission to promote Pharmaceutical Medicine. Robert hopes to be able to continue the excellent work and the achievements of his predecessor Cordula Landgraf, the former chair and to build on the experience of the working group to further establish strong collaborations with existing and new stakeholders.

He is an MD and certified specialist in Internal Medicine-Nephrology in Belgium. He has a PhD in Medical Sciences, is European Hypertension Specialist and Fellow of the Belgian College of Pharmaceutical Physicians. He was a Clinical Professor at the Department of Internal Medicine, University of Antwerp. He is member of different local and international scientific societies and was most recently president of the Belgian Association of Clinical Research Professionals (ACRP.be), now Healixia. He worked during many years as director of the department of Nephrology-Hypertension at Stuivenberg hospital in Antwerp, Belgium, before becoming general manager of one of the hospitals, belonging to the Hospital Network of Antwerp (ZNA).

He started a Clinical Pharmacology Unit for early phase development in Stuivenberg hospital in 1987, that was acquired later by the Swiss-based company Société Générale de Surveillance (SGS). As an investigator he was also involved in late phase clinical trials and in investigator driven epidemiological research. From 2007 until 2011 he was Managing Director of SGS Life Science Services Clinical Research.
Since then, he is continuing his activity as a consultant to the pharmaceutical industry. Currently he is Managing Director of Robert Lins Consulting and Project Director Respiratory Diseases for SGS Life Sciences. He is leading a working group at the Belgian ministry of health related to specialisation in pharmaceutical medicine/clinical pharmacology, leading to recognition of the specialty in Belgium in 2023. He is active as reviewer/editor of international journals in the field and published over 100 articles in international peer-reviewed journals.

**Robert Lins, MD, PhD, Robert Lins Consulting, Antwerp, Belgium**

## The Future of Clinical Trials, the Promise of AI and Key Trends

The future of clinical trials and research is closely linked to rapid advances in artificial intelligence (AI). In the recent IFAPP webinar on 30 January 2024, we took a closer look at how scientific developments and new technologies are impacting R&D and clinical trials for patients and society.

AI appears poised to revolutionise the landscape of clinical development and pharmaceutical R&D, impacting several areas that address operational excellence, automation and acceleration to reduce the time and cost of drug discovery through to first-in-human studies, randomised clinical trials (RCTs) and regulatory approval.

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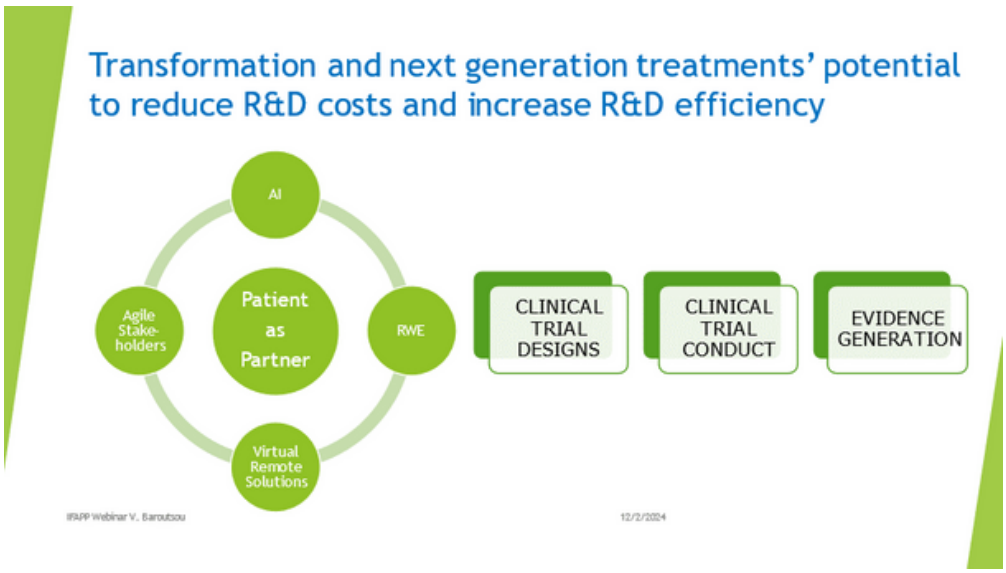


The use of AI in clinical development has primarily focused on operational efficiency, automation, and speed of execution in the following areas:

- Patient recruitment: AI can analyse electronic health record (EHR) data to identify suitable candidates for clinical trials.
- Virtual follow-up visits: AI can enable virtual follow-up visits, transforming traditional evaluation methods.
- Resource allocation: Predictive analytics tools help organisations allocate resources effectively.
- Real-world data (RWD): Integrating RWD into clinical trials complements results and provides a broader perspective.
- However, recent advances in scientific AI provide an opportunity to leverage modern analytics tools and novel data sources - such as omics, sensors, wearables, new and digital endpoints - to design more accurate and efficient trials.
- Generative AI (gen AI) and foundational models are driving innovation in pharmaceutical R&D by using AI-enabled platforms to predict 3D structures of molecules, leading to better preclinical assets and faster target validation.


*This illustration of artificial intelligence has in fact been generated by AI.*

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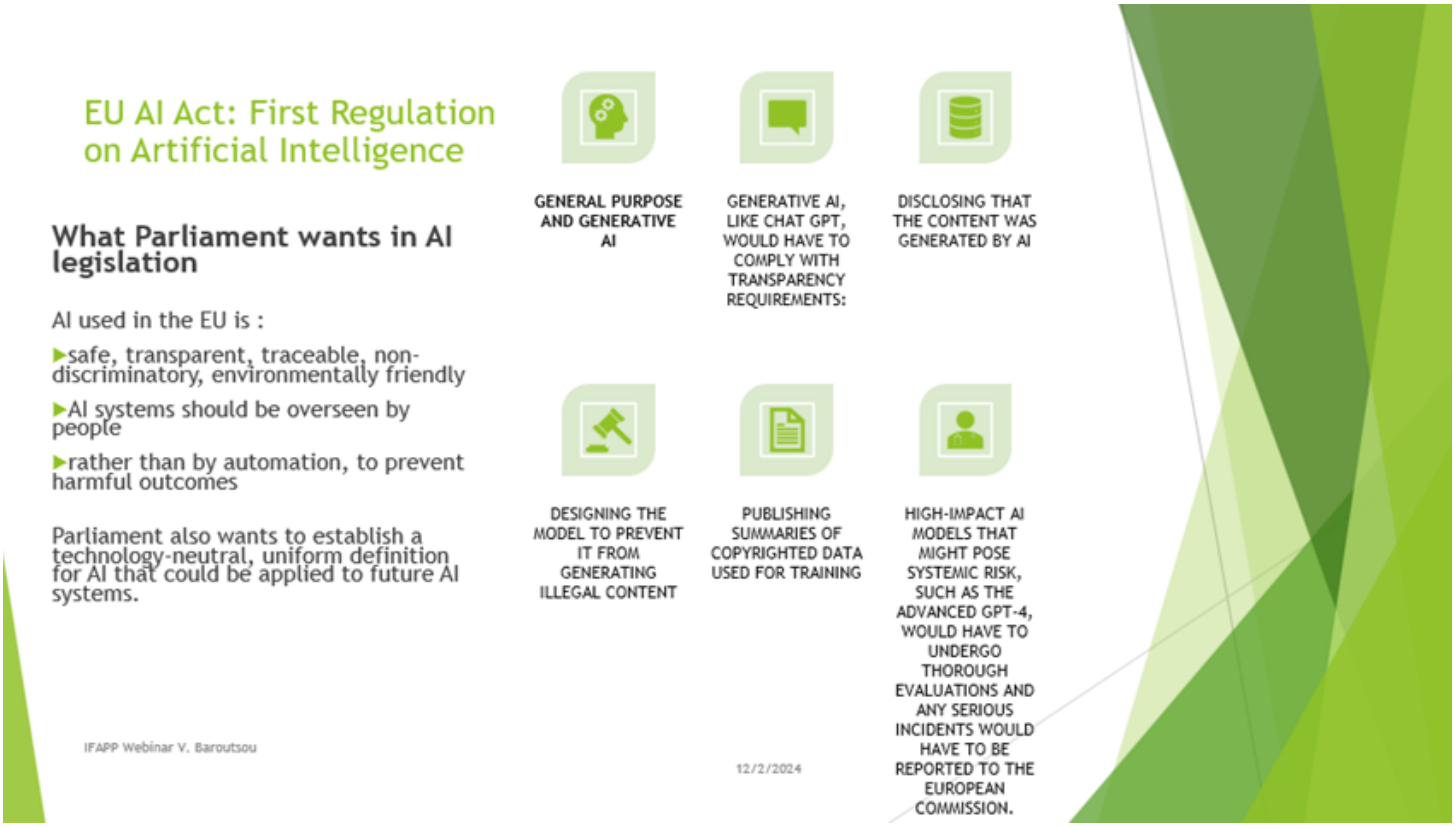
Precision medicine and targeted data require RCTs to demonstrate efficacy not only for the general patient population, but also for specific patient subgroups. Enrolling enough patients in trials for smaller patient populations can be challenging, so AI-assisted recruitment could be beneficial for safe and faster patient access.
Clinical development and AI could transform essential randomised clinical trials, currently perceived as a bottleneck due to longer approval times and high costs. AI can improve trial design, patient recruitment, safety monitoring, data quality and overall efficiency.
AI can bring value to patients by eliminating unpromising drug approaches during discovery and clinical development, thereby improving the patient experience during trials, minimising risks and contributing to more effective and safer treatments.

Historically, new technologies have often been beneficial to patients, investigators and clinicians. The R&D and clinical trial ecosystem is built on the ability of researchers and clinical investigators to use data from medicines and medical devices to improve patients' health.
Regulators and governments are issuing frameworks for AI, including guidance documents (FDA in the USA, MHRA in the UK), guidelines (EMA), legislation (European Commission) and executive orders (USA).




It is essential for AI in clinical research to ensure validation of algorithms, secure data interoperability, transparency and trust, while being able to monitor for hallucinations and "adverse events" through generative AI.

The World Health Organization's (WHO) new guidelines on large multimodal models recommend, among other things, mandatory audits of medical algorithms to ensure that they protect both data and human rights.

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Prudent use of AI under human oversight will make the use of AI safe. Responsible AI in medicine should:

- be subject to the same level of scrutiny as any clinical intervention, e.g., RCT.
- encourage multidisciplinary discourse and the development of a transparent, patient-centred approach to AI with an emphasis on diverse, accessible datasets and envision a future where AI meets the highest ethical standards.

In conclusion, AI should be seen as a democratising force to bring privileged medicine and research to a wider population because of its immense potential to transform clinical trials, improve evidence-based medicine and ultimately benefit patients by accelerating drug development and improving treatment outcomes.

**Dr Varvara (Barbara) Baroutsou**
President IFAPP

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## Advancing Artificial Intelligence Regulation through the Lifecycle

When first studying clinical research, we are presented with the classic drug development pipeline illustrations, but we are also confronted with its lengthy timelines and high levels of attrition. Undoubtedly, many innovative products have emerged from the pipeline in recent times such as biologics and advanced therapies, but what about the pipeline itself? Could innovation here help against mounting costs and protracted timelines?

One such innovation where hopes are aimed is Artificial Intelligence (AI) and Machine Learning (ML) and its potential in optimising many aspects of the management of the lifecycle of a medicine. Whilst both terms are used in commonality with one another, it is important to understand they have their differences. AI systems mimic human behaviour through their ability to analyse and make reasoned decision making in real-world environments. Whereas ML is one of the tools utilised in AI, built from algorithms trained on datasets creating models to enable identification of patterns aiding AI decision making. AI, as the umbrella term, also has the ability to learn from its interactions and improve its functionality.

Aspects of the lifecycle are already embracing AI and have found its benefits. In drug discovery, AI has helped in identifying novel drug target sites or those that could be repurposed (You, Y et al; 2022). The use of digital twins is another example where a virtual copy of processes or products is made allowing in silico analysis, e.g., of cellular response to drugs, simulation of dosing regimens, generation of virtual patients for placebo groups or sub-group analysis (Moingeon, P et al; 2023). There are also risks in AI approaches including disclosure and transparency in the models used, concerns on the potential of bias, and data integrity.

### EU Regulation of AI in Medicines Development

Regulatory guidance for AI and the medicinal product lifecycle has come under considerable focus as a result of the aforementioned concerns and the expected growth in this area. Most recently the EMA issued its draft 'Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle (EMA; 2023) (Figure 1).' At the outset two things are specifically highlighted in the draft. First, the EMA indicate future regulatory guidance will be published on risk management given the potential of systems to malfunction. Recommendations from the EMA Quality Innovation Group are also expected in relation to manufacturing of medicinal products. Second, that the Market Authorisation Holder (MAH) bears responsibility for all aspects of the AI utilised including algorithms, datasets and models.

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The paper is structured to consider each core stage of the lifecycle:

**1. Drug Discovery**
Here risk is said to be largely upon the sponsor but should results from this stage form part of a regulatory submission, then the non-clinical AI guidance should be followed.

**2. Non-Clinical**
AI/ML might benefit in reducing, replacing, or refining the use of animal models but where data contributes to the overall benefit/risk balance assessment then it should be analysed according to "a pre-specified analysis plan." Standard Operating Procedures should cover AI/ML application and where Good Laboratory Practice (GLP) is applicable consideration should be given to The Application of the Principles of GLP to Computerised Systems (no.17) and GLP Data Integrity by the OECD.

**3. Clinical Trials**
Good Clinical Practice is applicable to AI/ML systems, and it is here where we see one of the largest emphasis from the EMA on transparency with "full model architecture, logs from modelling, validation and testing, training data and description of the data processing..." to be made available as part of regulatory submissions. Encouragement is also given to publish models in an open repository prior to use in pivotal trials.

If AI/ML models are used to analyse clinical trial data, then they are considered part of the statistical analysis plan (SAP). Of note, where the guidance specifies pivotal trials "incremental learning" is not accepted, and any alterations to the SAP require regulatory approval.

**4. Product Information**
Whilst AI applications merit use in compiling medicinal product information, the EMA draft warns this should be alongside close human supervision to ensure documents are correct in both fact and syntax prior to regulatory submission.

**5. Post-Authorisation**
Interestingly here the guidance is seen to have a more flexible approach where incremental learning is seen to benefit models in their ability to classify and score severity of adverse event reporting and signal detection. AI/ML models used within the pharmacovigilance system remain the responsibility of the MAH to validate and monitor and should be aligned with Good Pharmacovigilance Practices.

**6. Technical Aspects**
Given AI/ML systems are built from data training sets fed through them, the datasets themselves should be of a balanced population and non-discriminatory. The draft stipulates sourcing and processing of the data including downstream activities should be fully traceable and documented in accordance with GxP. Considerations should also be given to representativeness, mitigation against class imbalance and against risk for discriminatory outcomes.

Use of train-test split, as an AI/ML systems model validation process, is strongly encouraged alongside traceable logs allowing assessment of model development over time. Whilst use of transparent models is preferable, the EMA does acknowledge this may not always be possible so rationale should be given when choosing non-transparent models as well as a risk management plan (RMP) to mitigate any issues. The RMP should include routine sampling of data for manual classification and define likely risks of fail modes of the model's algorithms.

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**7. Data Protection, Integrity and Ethics**

As with all personal data matters in the lifecycle, for AI they are to be kept and used in accordance with EU data protection legislation. The EMA specifies compliance of the systems data protection falls under the national competent authorities to supervise.

It cannot be ignored that, given the storage of data within the models, there is potential for malicious interference. Integrity preservation should be in place evaluating where potential vulnerabilities may exist and measures taken to mitigate identification of patients.

Expertise on ethical and legal aspects regarding AI systems should be in place early in development with implementation of the Assessment List for Trustworthy Artificial Intelligence for self-assessment (ALTAI). The European Commission established an expert group on AI to develop ALTAI where it is worth noting again measures on privacy, technical robustness and transparency are reiterated (EU Commission digital strategy; 2020).


*Figure 1: Lifecycle topics of the EMA draft reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*

As part of the EU Commission's endeavour to support uptake of AI, but ensure it is done carefully, safeguards are being brought in via the Artificial Intelligence Act. These measures include regulatory sandboxes, imposed limits on high-risk AI cases, support for SMEs, and sanctions for non-compliances. In addition, the new expert group has been tasked to 'advise and assist' with - of relevance to those in Pharmaceutical Medicine – to ensure the AI Act avoids overlap with the Medical Device and In Vitro Diagnostics device regulations.

The draft closed for comment December 2023 and is now being finalised. Given AI is evolving rapidly, however, it remains to be seen if the regulatory landscape will keep at pace with these changes not only in advancing management of the lifecycle but also in the protection of Public Health.

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Chair IFAPP Young Professionals Working Group

## Mind the Gap!

In the realm of career growth, investing in learning and training plays a vital role in expanding professional horizons. Being chosen by my employer, The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP), to attend a week-long training at the esteemed Faculty of Pharmaceutical Medicine (FPM) of the Royal Colleges of Physicians in the UK has filled me with anticipation for an enriching experience.
Besides the opportunity to enhance my professional skills, network, and learn how to run a charity organisation from the experts, the prospect of exploring the vibrant city of London for the first time held an abundance of promise.

Arriving at the FPM headquarters, I was instantly captivated by the friendly, yet professional atmosphere of all the staff starting from the CEO, Dr. Marcia Philbin, who received me with much welcome and a mouthwatering “Pret A Manger” sandwich platter!

The training programme was meticulously planned, covering a wide range of topics that were crucial to advancing my understanding of the Pharmaceutical Medicine education and career path in the UK. It provided insights into various aspects, including FPM strategy, operational management, effective governance, key ongoing projects, successful marketing, digital communications, attracting sponsorship, policy implementation, events organisation, the Diploma in Pharmaceutical Medicine (DPM) training, examinations setting up, and specialty training. Each day brought new insights and valuable takeaways that served as a steppingstone towards a deeper understanding of the Pharmaceutical Medicine specialty.

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Adding a new dimension to my journey, I had the chance to visit King's College London (KCL), where I had the pleasure to meet Professor Stuart Jones, the director of The Centre for Pharmaceutical Medicine Research (CPRM), and engage in thought-provoking discussions and updates on collaborating with MEAPP to raise awareness of Pharmaceutical Medicine and build capacities in the Middle East.

Yasmin with Dr Marcia Philbin, FPM CEO and Dr Assem el-Baghdady, MEAPP president and founder

I could not leave KCL without meeting the operations backbone of the CPRM, Claire Garner, who is known for her exceptional knowledge and unwavering dedication. I was fortunate to receive a briefing from "the always-smiling" Claire on the students' registration process and MOCK exams.

Talking about London itself, the city's vibrant energy, rich history, and iconic landmarks leave an unforgettable mark on any traveller, especially a first-timer. Stepping a foot in the bustling capital was a bit overwhelming, especially the slightly perplexing world of underground tubes and trains. The myriad of coloured lines, interchanges, endless corridors, and rush hour "organised" chaos made the struggle real!

Yasmin puzzled in the underground station bustle!

Amidst the maze of London tubes and trains, a peculiar announcement caught my attention; "Mind the gap". Pondering its meaning, beyond being a reminder to be cautious of the physical gap between the train and the platform, I couldn't unsee the metaphorical gap in Pharmaceutical Medicine knowledge and practice between the UK, Europe and the Middle East.

Pharmaceutical Medicine is advancing disproportionately, leaving many countries without adequate healthcare, dependent mainly on imported medicine, and suffering a dire shortage of new medicine development scientists.

By acknowledging this disparity, MEAPP was established with the vision to bridge this knowledge gap by enabling pharmaceutical professionals in the Middle East to gain accredited qualifications, skills, and knowledge, to ensure better healthcare outcomes for all and create a more equitable and inclusive society where knowledge is accessible to all.

In that essence, MEAPP is keen on establishing collaborations and partnerships (such as FPM and KCL), organising training programmes, and initiating knowledge exchange platforms so that professionals from the Middle East can benefit from professionals from the UK, which has long been recognised for its superior Pharmaceutical Medicine practices and strategies. This has started with the Building Capacity project funded by the British Council in Cairo and collaboration between KCL and the National Research Centre in Cairo (NRC), followed by the kick-off conference "Domiciliation of Medicine Development in Egypt" that was held in February 2023 in Cairo, Egypt, and was overwhelmingly received.

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Currently, MEAPP is planning its second Conference titled “Domiciliation of Medicine Development in the Middle East” with poster presentations from young researchers and prize awards for the best ones.

Just as the announcement in the underground reminds us to be cautious of the gap, let us be mindful of the gap in Pharmaceutical Medicine practice and take proactive steps to bridge it.
I am grateful to MEAPP and FPM for offering me this eye-opening experience, now I am a seasoned commuter ready to conquer London’s tube network!

**Yasmin Nagaty, Pharm.D, BCPS**
Senior Scientific Advisor

The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP) Registered Community Interest Company in England and Wales CIC # 12729033

## AMPIF Holds “Paving the Way for Pharma Medical Organizations Evolution” Conference


The Portuguese Association of Pharmaceutical Medicine (AMPIF) hosted a groundbreaking conference entitled “Paving the Way for Pharma Medical Organizations Evolution” on 9 November 2023 in Algés, aiming to foster innovation and transformation within the healthcare sector, as well as encourage collaboration and networking among professionals. This highly anticipated event gathered esteemed experts in the medical, pharmaceutical and political fields, including the National Authority of Medicines and Health Products, INFARMED, and Apifarma, the Portuguese Pharmaceutical Industry Association.

The conference's theme, "Paving the Way for Pharma Medical Organizations Evolution," reflects the industry's self-evolving nature and pivotal role on driving a positive change in healthcare. The impressive progress in the life sciences sector has determined that the pharmaceutical industry is capable of raising the bar with better prevention strategies, treatment approaches, and curing a huge spectrum of pathologies. Its necessary transformation is based on well-defined structural models, but also on the training of teams equipped with the necessary tools and resources to accelerate the pace of implementation of evolutionary models. In this transformational process, a more performance-based culture supported by a mindset of responsibility and empowerment will be essential.

AMPIF is dedicated to advancing pharmaceutical medicine in Portugal, and this conference represented a significant milestone in achieving this goal. The association represents healthcare professionals dedicated to Pharmaceutical Medicine, with different experiences and knowledge, who come together by sharing the same vision: a real impact on health and society, focused on communication and collaboration.

For the 2022-24 three-year period, the AMPIF board has made a priority to learn about, communicate and value the critical role of medical departments in Portugal. For this, a new study to update the latest data available on this topic, dated from 2017, was carried out.

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The main objectives were to characterise the size and composition of medical departments in Portugal, their current and future strategic areas and quantify their main activities. A response rate of 38 % was obtained, with 19 pharma companies answering the questionnaire. The main conclusions are highlighted in 3 points:

- A 50 % increase in the number of permanent employees in 42 % of the companies,
- Continuing medical education and the generation of insights are currently the priority areas of focus, with digital being the main focus for the next 5 years,
- Compared to 2018, more than half of the companies had an increase in the number of external interactions of their customer-facing functions.

AMPIF also presented the learnings of the roadshow held to the largest medical departments in the Pharmaceutical Industry in Portugal. The roadshow objectives were to present AMPIF, the 2022-2024 triennium programme, and gather insights into how AMPIF may help maximise the impact of medical departments on the Pharmaceutical Industry and society. Over the course of a year, visits to 11 medical departments were made. The main conclusions related to:

- Suggestions to promote Medical Affairs training for associates,
- Improving communication between peers from the different medical departments,
- Increasing the visibility of the medical department and its professionals' role and action within the pharmaceutical industry [JS1] and the health ecosystem in Portugal.

In this context, the 2023 Annual Conference followed a dynamic programme featuring keynote speakers and panel discussions, focused on 3 axes:

- Evolving roles in medical organisations: from existing capabilities to newskills required;
- Measuring success: from outputs, through outcomes, to impact;
- Building strong medical structures to succeed.

The format was of a meeting divided into three simultaneous sessions, each dedicated to one of the axes. Each session began with an intervention from one keynote speaker followed by a discussion with a group of experts. The meeting ended with a joint session, for sharing and discussion of the main reflections from each session.

In the "Evolving roles in medical organisations: from existing capabilities to new skills required" session, Stan Tsvirko, Digital Medical Affairs Head at Novartis US, was the keynote speaker and presented the growing importance of the role of medical departments in 3 vital areas for the future of the pharmaceutical industry: health data, research and innovation, and patient-centricity. The conversation brought together colleagues with experience in different areas of the pharmaceutical industry, from medical affairs, regulatory, research and clinical operations to human resources and talent management. Maria João Lourenço, HR Consultant; Maria Reis, Country ClinOps Manager at AbbVie; Sofia Oliveira, Executive Director Regulatory Affairs at MSD; Frederico Calado, Vice-President Global Real-World Solutions at Alira Health, and Ricardo Encarnação, Medical Director at Roche, reflected on the knowledge and skills needed to develop Pharmaceutical Medicine of excellence in the future. This reflection can be translated into a word cloud of the main knowledge and skills identified: analytical capacity and critical thinking about health data, gathering and managing insights, a "growth" and "agile" mindset, cognitive and emotional flexibility, cross-functional collaboration, digital, communication and negotiation skills.

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The session “Measuring success: from outputs, through outcomes, to impact”, began with Joana Santos Silva, Director of Innovation, ISEG-Executive Education, who addressed the main challenges faced by organisations in measuring the impact of Medical Affairs activities on health systems, along with emerging trends. The panel also brought together colleagues with experience in different aspects of Medical Affairs, Alexandra Stoffel, Medical Therapeutic Area Manager Cardiovascular, Novartis, Carla Gonçalves, Medical Director, Bayer Medical Director; Manuel Salavessa, Medical Engagement Director, Johnson & Johnson, and Maggie João, Executive Coach. The joint reflection highlighted the surrogate role of qualitative engagement metrics, the duality inherent in evaluating activities with a later impact, the needed balance between the number and relevance of metrics and objectives, as well as the relevance of evaluating the happiness of employees and medical teams.

The “Building strong medical structures to succeed” workshop, which aimed to provide a comprehensive understanding of the competencies and areas of activity of Medical Affairs in the pharmaceutical industry in the future, began with a lecture by Prof. Dr. Ghazaleh Gouya, IFAPP, on the same topic. In addition to the presence of GSK's Medical Director, Neuza Teixeira, this workshop also invited people from outside the medical departments and the pharmaceutical industry itself to share their views on these issues as external interlocutors. Specifically, this session heard from Prof. Dr. Ana Paula Martins, at the time President of Hospital de Santa Maria; Carlos Aguiar, Cardiologist at Centro Hospitalar de Lisboa Ocidental - Hospital de Santa Cruz, Miguel Rodrigues Simões, Senior Manager at Deloitte, and Miguel Vieira, Business Unit Director at Gilead. The skills to be maintained and/or developed by people in medical departments, identified by the members of this workshop, include scientific acumen and credibility, communication skills, greater involvement in clinical research, the use of new digital tools, an understanding of clinical governance models (e.g., local health units model) and strategic vision, from a perspective of complementarity between the different departments within the same company.

In summary, we believe we’ve taken another relevant step in the long path to advancing Pharmaceutical Medicine in Portugal.

**Alexandra Stoffel, Antonio Soure, Bruno Dias, Carla Gonçalves, Helena Vieira, Inês Cardoso, Lucas Morais, Mafalda Nogueira, Manuel Salavessa, Neuza Teixeira, Paula Martins de Jesus, Susana Marques**
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# EUPATI Italy (Accademia del Paziente Esperto EUPATI): a Project for Informed Patients, Caregivers and Citizens

In 2014, the Accademia del Paziente Esperto Eupati Aps, was founded with the aim of disseminating the European EUPATI project in Italy. EUPATI, European Patients' Academy on Therapeutic Innovation, is a patient-led initiative that uses training courses, educational material and an online public library for empowering patients to engage more effectively in the development and approval of new treatments and become true partners in pharmaceutical research and development.

*EUPATI Italy Fellows 2024*

**Italian EUPATI Fellows and Training Course for Patients and Caregivers**

In Italy there are now 140 EUPATI fellows who, thanks to the training on the topics of Research and Development of innovative therapies, have acquired the right skills to be able to collaborate alongside doctors, researchers and stakeholder involved in the world of health.

For those of them (and they are the majority) who represent patients, it will also be possible to pass on what they have learnt in the course, within their own associations and in any appropriate places for involving and strengthening the role of the patient and caregiver.

**Our Partners**

AdPEE realises multi-stakeholder projects aimed at training of patients and caregivers in collaboration with **AIFA - Italian Medicines Agency -** (signed an MoU in 2014 and reconfirmed in 2019), under the patronage of the **Istituto Superiore di Sanità and Farmindustria**, and with the support of many important **pharmaceutical companies** (https://accademiadeipazienti.org/partner/).

Also, we signed a Memorandum of Understanding with San Raffaele Hospital in Milan for the inclusion of a Patient Expert EUPATI (PEE) in the Ethics Committees, and with S.I.F. (Italian Society of Pharmacology) for training activities and scientific dissemination.

Training Courses for Patients and Caregivers: EUPATI Training Course (which this year will reach its 5th edition), in-depth training modules and workshops dedicated to PEEs.

We carry out activities aimed at recognising the figure of the PEE and at engagement, information, communication, and scientific dissemination activities about Drug R&D.

You can find some examples of the communication campaigns by AdPEE at this link https://accademiadeipazienti.org/progetti-speciali/.

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**AdPEE and the European Project IMI FACILITATE**

Since 2022, AdPEE has been part of the FACILITATE project. (https://www.youtube.com/watch?v=IxOqKuEm-Mc&t=336s ).

FACILITATE - Framework for clinical trial participants data reutilization for a fully transparent and ethical ecosystem - is a European-level initiative to give clinical trial participants access to their personal health data. The project is coordinated by UNIMORE, EUPATI Italy, and Sanofi, a multinational biopharmaceutical company. The FACILITATE Consortium includes 27 partners from 17 Member States, including patient associations, hospitals, universities, subject matter experts, and members of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

**New Challenges for 2024**

On top of the next edition of the Italian EUPATI course, which is scheduled for April 2024, an in-depth course dedicated to medical devices has also just started.The course entitled "DM (dispositive medici/medical devices) Universe: from Design to Patient Use" is the new Training Course promoted by EUPATI's Expert Patient Academy, in collaboration with Confindustria Medical Devices (Confindustria is the most important association representing manufacturing and service companies in Italy).

**Dominique Van Doorne** – Medical Endocrinologist, Board member of Accademia del Paziente Esperto EUPATI aps - Italy

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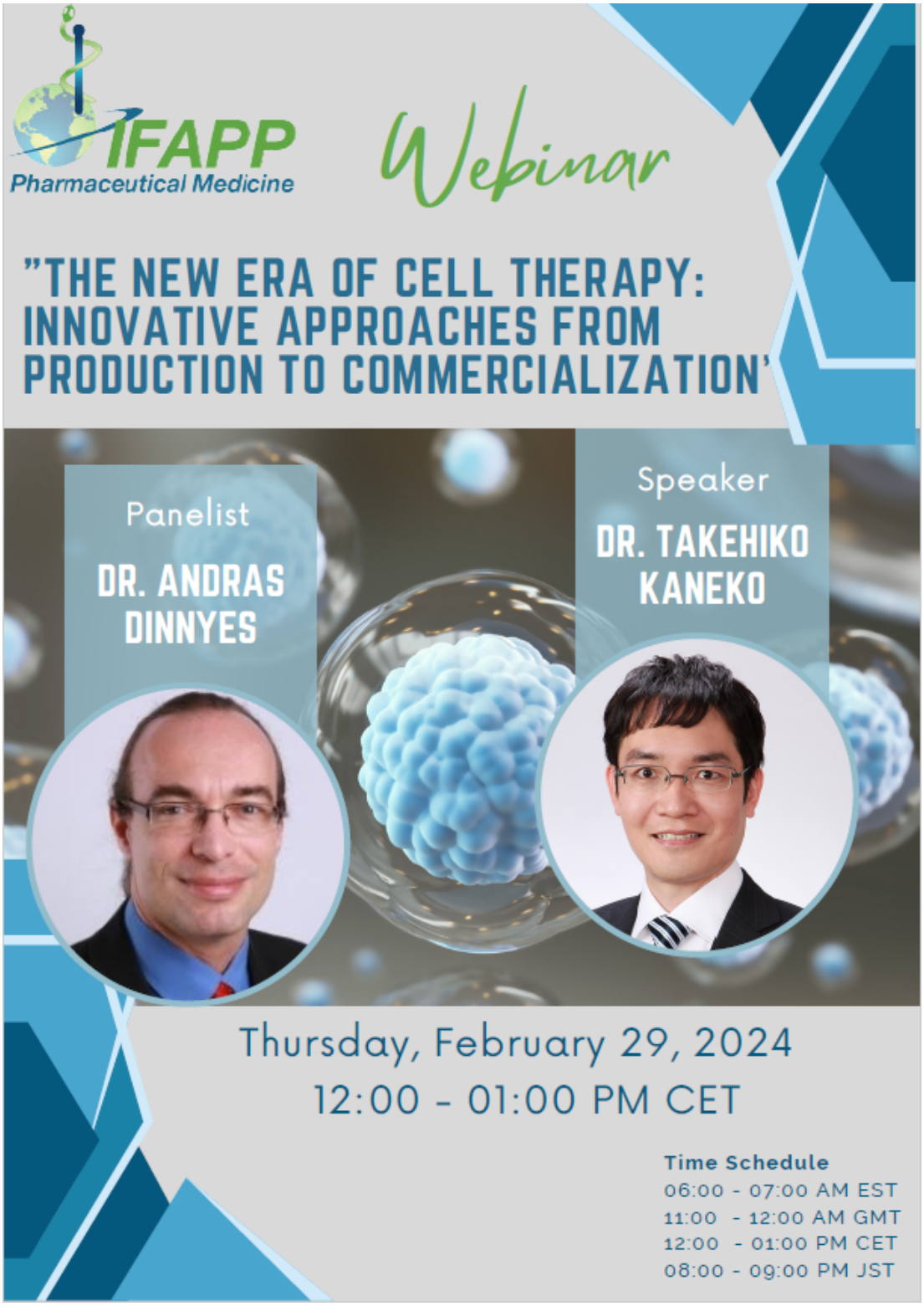

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## Webinar

## "THE NEW ERA OF CELL THERAPY: INNOVATIVE APPROACHES FROM PRODUCTION TO COMMERCIALIZATION"

In recent years, the medical field has witnessed revolutionary advancements in cell-based therapies. In this webinar, we delve deep into the latest updates and efforts in the manufacturing, quality assurance, clinical development, and commercialization stages of cell therapy. We will elaborate on how it differs from traditional pharmaceuticals, highlighting its unique features and challenges. By inviting experienced experts as our guests, we offer a vibrant platform for discussions on the potential implications and future prospects of this domain.

Speaker

**DR. TAKEHIKO KANEKO**

Register in advance for this webinar

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

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## THE FLAG

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**IFAPP Communication Working Group**
Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Francesco Butti, Brigitte Franke-Bray, Anna Jurczynska, Rita Lobatto, Hasan Mahmood, Kotone Matsuyama, Helio Osmo, Joanne Ramsey, Alexandra Reis Stoffel and Johanna Schenk (IFAPP TODAY Editor-in-chief).

IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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