IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

Breaking News: "Pharmaceutical Medicine/Clinical Pharmacology" New Specialty for MDs in Belgium

On October 31st, the Ministerial Decree was published regarding the creation of a new specialty for Medical Doctors in Belgium: physician-specialist in Pharmaceutical Medicine/Clinical Pharmacology.

This is a major milestone in the further professionalisation of this important role and will have significant impact for future talents in Belgium and for our health eco-system. It will strengthen research & development activities and contribute to the correct use of medicines, all to the benefit of patients.

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Belgium joins other countries in Europe to recognise Clinical Pharmacology as a specialty but it's only the fourth country in Europe after UK, Switzerland, and Ireland to recognise Pharmaceutical Medicine as well.

A working group, bringing together representatives from industry (via Healixia) and from academia, has driven this initiative since 2017; building further on the work already done by earlier working groups in 2004-2010.

Next step will be the set-up of this 4-year educational track for MDs in Belgium, which will continue to be a co-creation between industry and academia.

Healixia is the Belgian community of all professionals active along the life cycle of medicines, medical devices, in-vitro diagnostics & other health-related products. Members are active in research & development (including pre-clinical, early clinical, and later phases), medical affairs, safety, regulatory affairs and market access in industry, academia, investigator sites, authorities, regulatory bodies or in consultancy. Healixia is a member of IFAPP since the start of Healixia in 2020; and build further on the legacy of BeAPP (Belgian Association of Pharmaceutical Professionals and former IFAPP member), ACRP.be (Belgian Chapter of ACRP), BRAS (Belgian Regulatory Affairs Society) and BAPU (Belgian Association of Phase I units). More info on www.healixia.be.

Healixia is very proud to be part of this journey and realising one of its major objectives: ensuring the further professionalisation of pharmaceutical professionals in Belgium.

Dr. Erik Present, President Healixia
Email: info@healixia.be

End of Year Message from the President

Dear Valued Members, Stakeholders, and Colleagues,

As we approach the end of 2023, I would like to take this opportunity to thank you for everything you have done to make IFAPP an evolving collaborative, dynamic space to build on rejuvenating and reinvigorating the organisation by introducing a multidisciplinary and inclusive Pharmaceutical Medicine culture that focuses on the development of next generation leaders and the future of IFAPP.

We have come through a year filled with both challenges and successes. The IFAPP Board managed the challenges and defined the IFAPP strategy and operational plans for 2023–2024, which were debated during the IFAPP Regional Meetings in Amsterdam and Tokyo and at the MEAPP conference in Cairo.

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We have succeeded this year in the following:

- Publish ten issues of the IFAPP TODAY Journal, thanks to Dr. Ghazaleh Gouya and the IFAPP Communication Working Group.
- Successfully conducted eight IFAPP educational webinars, thanks to Dr. Birka Lehmann and the IFAPP Education & Certification Working Group.
- Contributed to WMA, CIOMS, and ICH consultations and meetings, thanks to Prof. Kotone Matsuyama and the IFAPP Ethics Working Group.
- IFAPP joined a fruitful collaboration with the PharmaTrain Federation (PTF) and the Faculty of Pharmaceutical Medicine (FPM) on the PharmaTrain Syllabus Revision (PTSR) Project. IFAPP, PTF and FPM were the sponsoring bodies of the PTSR Coordination Group (CG). Dr. Birka Lehmann, as the IFAPP liaison with PTF, I, as the IFAPP liaison with FPM and Assoc. Prof. Joanne Ramsey as the PTSR CG IFAPP liaison were actively involved and contributed to the update, integration, and harmonisation of the revision of the syllabus.
- Announcement of the new IFAPP sponsorship plan.
- Launch of the new 2024 IFAPP Fellowship Awards.
- We are upgrading our website and gearing up for the International Conference on Pharmaceutical Medicine (ICPM) 2024.

In parallel, we are motivated on creating attractive offerings for a future-proof career growth for the young professionals, based on the early works of Cordula Landgraf, Pharmacist, and Dr Annette Mollet with the IFAPP External Affairs & Young Professionals Working Groups.

All these initiatives, milestones, and activities would not have been possible without the unprecedented dedication and commitment of the IFAPP Board leadership, IFAPP Working Groups, and IFAPP National Member Associations (NMAs) and Individual Affiliates (IA) collaboration.

It has been quite reassuring for me to know that I can count on the IFAPP Executive Board Members, Anna Jurczynska, PhD, Dr. Marco Romano and Nikos Tsokanas, BSc (Hons), MSc, MBA, to navigate the hindrances and challenges and support IFAPP Scientific Officers and Chairs of the IFAPP Working Groups.

2023 was a year of important changes. We were adapting and improving, learning, and adjusting. 2024 is around the corner. Like 2023 there will be challenges and changes and we will be strengthening our communication and collaboration to support you and address needed adjustments.

Please allow me to extend my personal and genuine appreciation to the IFAPP Board Members for their energy, talent, hard work, and innovative ideas that inspire us to recreate the future of IFAPP.

Working with our NMAs and IA members this past year has been a great experience, and we are proud to have you all with us.

I am deeply grateful for all the efforts you have shown, and I share my best wishes with you and your families for a healthy, peaceful, and creative 2024.

Looking forward to further promoting Pharmaceutical Medicine with you all, our partners, and stakeholders.

Thank you for your engagement and trust in IFAPP.

Dr. Varvara Baroutsou
IFAPP President

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2024 IFAPP Fellowship Awards
Fostering Excellence and Professional Diversity

Dear Colleagues,

It is with great enthusiasm that I write to invite you to participate in the new IFAPP Fellowships programme. All award category descriptions, criteria, and submission information are listed below.
Being a fellow of IFAPP is not only a recognition of one's personal contribution to Pharmaceutical Medicine, but also a way to belong to a dedicated group of distinguished professionals who demonstrate scientific integrity and excellence in research, education, and leadership.
The three fellowship categories and application requirements for the awards are:

1. Scientific Leadership in Pharmaceutical Medicine (PM) for Senior Candidates (experience > 15 years in PM roles)

- Nominee's current curriculum vitae.
- Copy of an academic diploma (MD, PhD, PharmD, Biomedical, MPH, healthcare professional diploma).
- Short list of publications: minimum 10 publications as co-authors in peer-reviewed journals.
- A nomination letter from an IFAPP Board Member or NMA Board Member.
- Interview with IFAPP Fellowship Award Committee Members.

2. Scientific Excellence in Pharmaceutical Medicine (PM) for Mid-career Candidates (experience of > 10 years and ≤ 15 years) in PM roles)

- Nominee's current curriculum vitae.
- Copy of an academic diploma (MD, PhD, PharmD, Biomedical, MPH, healthcare professional diploma).
- Shortlist of publications: minimum 5 publications as co-authors in a peer-reviewed journal.
- A nomination letter from an IFAPP Board Member or NMA Board Member.
- Interview with IFAPP Fellowship Award Committee Members.

3. Rising Star in Pharmaceutical Medicine (PM) for Early Career Candidates (experience of > 3 years in PM)

- Nominee's current curriculum vitae.
- Copy of an academic diploma (MD, PhD, PharmD, Nursing, Biomedical, MPH, healthcare professional diploma).
- Shortlist of publications: minimum 2 publications as co-authors in a peer-reviewed journal.
- A nomination letter from an IFAPP Board Member or NMA Board Member.
- Interview with IFAPP Fellowship Award Committee Members.

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The deadline for submitting your application is Friday, January 26, 2024.

All nominations should be submitted according to the application instructions provided above by email to anna.jurczynska@ifapp.org and varvara.baroutsou@ifapp.org. If you have any questions about the nature of this award or the selection process, please feel free to contact Anna Jurczynska, PhD, IFAPP General Secretary (anna.jurczynska@ifapp.org) for additional information.

The IFAPP Awards Reception, where all awardees will be recognised, is scheduled to occur at the ICPM 2024 in Amsterdam in October.

Thank you in advance for your participation in this important process; your candidacy for these prestigious awards is greatly appreciated.

Dr Varvara (Barbara) Baroutsou

Varvara Baroutsou

IFAPP President

2024 IFAPP Fellowship Awards

The IFAPP Fellowship Awards Programme recognises excellence and honours individuals who have distinguished themselves in their Pharmaceutical Medicine career stages.
The unique title IFAPP Fellow is a distinction of development within the IFAPP community.
It represents the extraordinary achievements of IFAPP healthcare and biomedical professionals.
The application period for becoming a Fellow of the IFAPP in 2024 is now open until January 26, 2024. We encourage you to begin preparing your submission.

The IFAPP supports applications from all our members, including National Member Associations and Individual Affiliates. There are no age criteria. Please refer to the application categories and guidelines for familiarisation.
Being elected as an IFAPP Fellow indicates your level of expertise and contribution to the field of Pharmaceutical Medicine.

Why should you apply?
The IFAPP Fellowship is a symbol of excellence; all applications will be reviewed by the IFAPP Fellowship Award Committee.

- Be recognised and respected by the global IFAPP community.
- Be visible for opportunities to become more involved in the IFAPP Working Groups, IFAPP activities, and events.
- Be part of a unique network of more than 6,000 professionals from 32 countries.
- Exclusive access to an IFAPP dedicated ceremony during ICPM 2024.
- Receive a certificate and prize.
- Announcement of the awarded IFAPP Fellows in the IFAPP TODAY Journal, on LinkedIn, and the IFAPP website.
- Use the IFAPP Fellow title in your signature.

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How to apply

The criteria for becoming an IFAPP Fellow involve a selection process assessed by the IFAPP Fellowship Award Committee, which reviews candidates' scientific contributions, publications, and professional achievements.

The application is open to all healthcare professionals and biomedical scientists in the field of Pharmaceutical Medicine. There are three tracks to become an IFAPP Fellow:

- Senior Professional Candidates
- Mid-career Professional Candidates
- Young Professional Candidates

What happens next?

- Your application will be reviewed by the IFAPP Fellowship Award Committee
- You will be invited to an interview in March 2024.
- You will be informed of the decision with your application by the end of June 2024.
- If successful, you will be informed of the award ceremony at the upcoming ICPM 2024 next October by mid-July 2024.

The deadline for submitting your application is Friday, January 26, 2024.

If you have any questions about the nature of this award or the selection process, please feel free to contact Anna Jurczynska, PhD, IFAPP General Secretary at anna.jurczynska@ifapp.org for additional information.

Pharmacovigilance - Not Important Enough for IFAPP?

Pharmacovigilance is defined by the WHO (World Health Organization) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

Pharmacovigilance (also known as drug safety) plays a major role for established drugs but also in the research and development phase of new compounds (where these activities are usually called clinical safety).

As the WHO on their website rightly emphasise, medicinal products may also have side effects in addition to their benefits, some of which may be undesirable and/or unexpected.

They add that, of course, all medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorised for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time.

Indeed, pharmacovigilance activities need to take place in all phases of drug development - pre-clinical phase, clinical trials and post-marketing area. Each phase is important for ensuring the safety of medicines and subsequently for the safety of the patients:

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Phase	I	II	III	IV	Spont., NIS etc.
No. of participants	~ 20 to 80 (male) participants	~ 50 to 500 patients	~ 500 to 10.000 patients	>1.000 to several ten thousands	Ten thousands to millions
Duration	weeks to months	months	months to years	years	years/decades
Milestones	pharmacokinetics, pharmacodynamics, tolerability	dose-finding, effectivity, tolerability	effectivity, tolerability, side effects, interactions	rare side effects, long-term use	very rare side effects, long- term use

The drug development process is usually mainly focussed on efficacy. However, even if a new compound has proven efficacy, it might cause serious side effects. The earlier they get detected the better (for the further course of the development programme, for the budget and mainly for the study participants and patients).

During the last decades a number of drugs failed to enter the market although they might have shown efficacy/effectiveness in clinicals trials; in particular first-in-man studies and studies with inadequate dose escalation schemes were seen to carry a high risk to harm patients. And there are also numerous examples where a drug has been on the market for a number of years but finally had to be withdrawn (from particular countries/regions or worldwide) due to severe side effects, such as astemizole, benoxaprofen, cisapride, clobutinol, ranitidine, rofecoxib or sibutramine.

Involving pharmacovigilance experts as substantial partners in all phases of drug development and marketing, might be an asset to prevent sudden unpleasant surprises. Pharmacovigilance, as one area of pharmaceutical medicine, is a specialist discipline where the personnel is preferably characterised by a good scientific understanding on the one hand, and on the other hand by a profound knowledge of the respective legislative backgrounds (in order to finally meet the regulatory authorities' provisions). Pharmacovigilance legislations differ from region to region and are sometimes not easy to interpret. They tend to become more complex during their further evolution, and completely new tools (such as AI, ChatGPT, etc.) could probably not be integrated yet.

Besides acquiring an appropriate scientific education, drug safety staff needs to get adequately trained on all relevant aspects of this specialty field in order to accomplish their tasks in a solid and reliable manner. Considering that the safety profile of a broadly sold

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drug doesn't stop at borders, streamlining the educational basis across countries might be beneficial; the same holds true for the sharing of information and work experiences amongst each other in order to ensure best patient safety (an expression that some companies have started to add as a subtitle to their pharmacovigilance department).

Hence, pharmacovigilance represents an important element of pharmaceutical medicine. Nevertheless - IFAPP does not have a pharmacovigilance (PV) working group (yet). **What are your thoughts? Is pharmacovigilance important enough to become subject of an IFAPP Working Group? And are you interested in joining such an IFAPP PV Working Group? What aims/projects should the IFAPP (as an umbrella organisation) address with regard to PV?** I look forward to hearing/reading about your point of view. E-mail me to: Contact@BoosConsulting.de

Monika Boos, M.D., Ph.D., LL.M.
Individual IFAPP Affiliate

IFAPP Education and Certification Working Group (ECWG) - Report 2022-2023

From December 2022 till November 2023 the IFAPP ECWG realised eight webinars and one two-day course. The topics covered ranged from conducting clinical trials to post-approval and reimbursement issues, and information on activities of national member associations.

We started in December 2022 with **Innovative option for course providers**, followed by **Vara and AI in Breast Cancer Screening** in February 2023. The two-day **Introduction to the new EU CTR** in March 2023 was followed by **Key Principles for Electronic Product Information** in the EU in April 2023. In May 2023 an in-depth review of **Connect4children** was presented. In June 2023 the webinar on **HTA requirements/German perspective** was followed by a webinar on **Diversity in CT**. The September webinar was dedicated to the information on IFAPP Reports on Regional Meetings and updates from the IFAPP Communication WG and Young Professionals WG. In October 2023 the **NMA of the Philippines** (PCPM) gave an update of their work in respect of pharmaceutical medicine. The last presentation in 2023 will be dedicated to AI in pharmacovigilance.

We received 870 registrations for all webinars (December 2022 – October 2023) but only 470 participants joined the webinars.

We hope to improve the relation between future registrations and participations.

The participants of the webinars reflected the global community of IFAPP.

In 2024 webinars are planned for each month starting with "The New Era of Cell Therapy: Innovative Approaches from Production to Commercialisation", giving updates on the EU CTR and what will happen in the HTA arena, and other hot topics.

Birka Lehmann, MD, PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

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Ten Years Later: Anniversary Edition of the Medtech & Pharma Platform Annual Conference

On 27 September 2023, the Medtech & Pharma Platform (MPP) Association, an inter-sectoral industry association focused on combined products, celebrated the 10th anniversary edition of its annual conference in Basel, Switzerland. Themed "Therapeutic Innovation with Combined Products – Advancing Patient Care", the conference's programme included important aspects related to the combined use of medicinal products, medical devices, and software components. Over 200 attendees from various industry sectors, regulatory bodies, patient groups, and academia across Europe and the United States exchanged different perspectives on the current regulatory framework for combined products and how to foster synergies in future.

The conference was opened by MPP President Shayesteh Fürst-Ladani (SFL) and Ruth Foster (MSD), Chair of the MPP2023 Programme Committee. Michael Berntgen (EMA) also opened the event, acknowledging MPP's crucial role in healthcare and emphasising the need for dialogue across sectors and stakeholders in the field of combined products. He highlighted the intricate drug-device combination EU ecosystem and the MPP's contribution in addressing regulatory challenges through collective efforts.

The MPP President moderated a panel featuring James Bertram (FDA), Michael Berntgen (EMA), Karoline Mathys (Swissmedic), David Haerry (EATG), Theresa Jeary (BSI) and Andreas Emmendörffer (Roche), in which perspectives on the regulation at the international and regional level were exchanged. It was highlighted that combined products are challenging established regulatory pathways, incentivising regulators to adapt. In this context, the need for a harmonisation of pathways at international level was emphasised, and the necessity of harmonising terminology as a pre-requisite to achieving greater global harmonisation of standards applicable to combined products.

Early patient involvement by industry actors and regulators was also identified, including important inputs on clinical endpoints, and conducting co-designed studies in clinical trials. The absence of a single harmonised framework for combined products in the EU remains a challenge and more work across actors would be needed at the interface of different regulations.

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A **digital health** session, moderated by Nathalie Schober-Ladani (SFL) and Ruth Foster (MSD), presented different perspectives from authority, industry, and patients. Samuel Gavillet (SFL) provided an overview of key digital health policies in Switzerland and the EU. Petra Leroy-Čadová from the European Commission presented the IHI project, the world's largest public-private partnership in the biotech sector, emphasising a cross-sectoral approach. Cécile Tardy from EUPATI Switzerland emphasised the necessity to view patients holistically, improving patient-centricity by considering their perspectives as individuals before being patients. Fatima Bennai-Sanfourche (Bayer) concluded the session with a presentation on the use of digital health technologies in clinical trials, highlighting key considerations, challenges, and limitations.

Another session focused on the **regulatory assessment of combined products** in the EU, including current challenges, and was moderated by Mike Wallenstein (Novartis) and Christiana Hofmann (Anteris by Kymanox). Ilona Reischl (AGES) highlighted challenges with the Medical Devices and In Vitro Diagnostic Regulations (MDR/IVDR) and proposed a tailored approach to improve clarity and guidance at the legislations' interfaces. Theresa Jeary (BSI) discussed common issues related to the applicability of Art. 117 of the MDR and the management of changes, and stressed some of the limitations faced by Notified Bodies under the current legislation. Jasmin Barman-Aksözen (SGP) shared the experience of SGP as the first patient group invited to a CHMP review and emphasised the importance of early patient involvement.

The closing session focused on **companion diagnostics** (CDx) and was moderated by Marie-Claire Beurier (Roche) and Marisa Papaluca (Imperial College London). It featured Prof. Antoni Bayes-Genis (Institut del Cor) who discussed how natriuretic peptides can support the diagnosis of heart failure. Celine Pallaud (Novartis) highlighted the increasing use of CDx in precision medicines, presented a case study, and emphasised the need for harmonised requirements for the IVDR implementation. Falk Ehman (EMA) underscored the significance of companion diagnostics and the need for a robust framework and collaboration between relevant stakeholders for the evaluation/validation of medicines and CDx.
The day concluded with remarks by the President and the Programme Committee Chair, followed by a speech by Lukas Engelberger from the government of the Canton of Basel-Stadt and President of the Conference of Health Directors on the industry's importance in healthcare.

Authors:

Nathalie Schober-Ladani, MD, LLM,
Senior Director Head Public Affairs
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Early Clinical Trials - Opportunities for Specialisation

The current GPMed course in cooperation with the Medical University of Vienna offered a diverse overview of the methods that can be used to conduct early clinical trials in addition to the classic phase I study design.

Modelling in Drug Development

Drug development is a costly and time-consuming process, with many candidates failing in clinical trials. To minimise this risk, models and simulations are increasingly used in clinical trials. Ass. Prof. Dr. Iris Minichmayr of the Department of Clinical Pharmacology at the Medical University of Vienna describes various models used in drug development to predict interactions between drugs, diseases and patients. These models help to describe exposure, efficacy, toxicity and disease progression. In early clinical trials, different models are used depending on the research objective. Population pharmacokinetic models allow simultaneous analysis of data from all patients, while systems biology models are used at the cellular level to improve the understanding of biological systems. The choice of model for simulating clinical trials depends on the available data. These models are used in the development of new drugs as well as in the approval and expansion of existing drugs.

Beyond First in Man - Conventional and Innovative Phase I Studies in Humans

Phase I trials are the basis for any marketing authorisation. But by then, many drug candidates are abandoned in the course of clinical trials. How can this risk be minimised? In his presentation, Professor Markus Zeitlinger of the Department of Clinical Pharmacology at the Medical University of Vienna showed numerous examples of how these studies can provide important insights beyond their classic definition. Complex study designs such as the "umbrella trial" and the "basket trial" make it possible to investigate different drugs or groups of people with similar genetic mutations and different diseases.

Sometimes studies are limited by small patient populations or complicated questions. In such cases, scientific evidence is obtained indirectly. For example, in one study the pharmacokinetic profile of an antibiotic was investigated in patients with tonsillitis or prostatitis following infection with gonorrhoea bacteria by applying the drug ex vivo to harvested organs and measuring the bacteria in the tissue using microdialysis to obtain the corresponding effect-time profile at the correct site of action.

Microdosing allows to measure the pharmacokinetics of drugs in humans after administration of very small doses. A feasibility study with an antibiotic has shown that microdosing in combination with microdialysis can be a potentially useful tool for predicting the pharmacokinetics of therapeutic doses at the target site in the clinical development of antimicrobial drugs.

In topical phase I trials, particularly in ocular disease, the short residence time of the drug on the ocular surface, poor penetration through the ocular surface, toxicity of preservatives and difficult-to-determine pharmacokinetics present particular challenges. For example, in a study of dry eye patients, the effect of drops coupled with high molecular weight carriers to extend ocular surface residence time was investigated by measuring changes in tear film thickness.

Imaging techniques such as positron emission tomography (PET) are also becoming increasingly important in phase I trials. This can be used to characterise ADME (absorption, distribution, metabolism, and excretion) processes throughout the body. The disadvantage is that, in addition to the technical infrastructure, a radiopharmaceutical is also required for the scan.

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Specifics of Phase I Studies in Participants with Hepatic/Renal Impairment

Phase I studies in hepatic and renal insufficiency are particularly challenging. Péter Karacs, Programme Director at Celerion, provided an overview of important study design criteria for these special population studies. Careful selection of inclusion and exclusion criteria is critical because many patients are already taking multiple medications and are severely ill. Severely impaired patients are difficult to recruit, so study sites should be flexible regarding timing. Smokers should be accepted as potential participants, as many patients with liver dysfunction smoke. Other challenges include verifying that healthy controls meet patient criteria, monitoring concomitant medications, assigning patients to the correct cohorts based on degree of impairment, and longer study duration due to the higher number of patients enrolled per cohort according to revised FDA guidelines.

Phase I Studies - an Austrian Perspective

"Scientific research and clinical care of patients cannot be considered separately," Univ. Prof. Dr. Richard Greil, University Clinic for Internal Medicine, Landeskrankenhaus Salzburg, said in the final lecture of the evening. Worldwide, 744,000 studies are registered with the WHO, of which about 51,000 are in phase I - with oncology studies making up for the largest share. In Austria, about 8 % of all trials are in phase I, with oncology dominating here as well. For the centres, it is important to be able to draw on as large a patient population as possible in order to be attractive to the industry as a research location and to have enough suitable study participants for later clinical phases. According to Greil, only a few centres in Austria are able to recruit enough patients and enrol them in studies. At the Salzburg site, 43 phase I studies have been conducted, 11 are currently ongoing and 4 more are scheduled to begin this year. The personal commitment of the researchers is important in order to be able to conduct the studies at their own site.

Author: **Anja Baumgartner-Reitz**, Senior Communication Specialist, MSD Austria

GPMed
GESELLSCHAFT FÜR PHARMAZEUTISCHE MEDIZIN E.V.

Left to right: Dr. Dejan Baltic, AMGEN Medical Director; Prof. Dr. Richard Greil, University Clinic for Internal Medicine, Landeskrankenhaus Salzburg; Prof. Dr. Markus Zeitlinger, Department of Clinical Pharmacology at the MedUni of Vienna; Ass. Prof. Dr. Iris Minichmayr, Department of Clinical Pharmacology at the MedUni Vienna; Péter Karacs, Programme Director at Celerion

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The Crucial Role of a Comprehensive Clinical Development Plan in Navigating Medical Device Development as outlined in MDR 2017/745

Clinical Development Plan

In the dynamic landscape of medical device development, strategic planning plays a key role in guiding a product from conception to marketing authorisation. Under the Medical Device Regulation (MDR) 2017/745, Annex XIV, paragraph 1a highlights the importance of a clinical development plan within the broader clinical evaluation plan. However, this document is not just a regulatory requirement; it serves as a cornerstone for the success of any medical device company.

A well-designed clinical development plan should go beyond the confines of a compliance checklist. It should be a strategic compass that guides the entire product development journey. Starting with a clear vision, often manifested in a target product profile, this plan enables reverse engineering of the entire development process. By visualising the product in the marketplace, companies can work backwards to outline the steps needed to get there.

This reverse approach provides invaluable insight into the timelines, budgetary considerations and human resources required for successful market approval. It serves as a roadmap that keeps the team focused on a common goal and promotes efficient communication and collaboration. In addition, by seamlessly integrating regulatory requirements into the development plan, companies can ensure compliance while streamlining the overall process.

By designing the clinical development plan early in the product ideation phase, companies can increase their competitive advantage. It provides a proactive framework to address potential challenges and hurdles and offers flexibility to adapt to the evolving regulatory landscape.

In essence, the clinical development plan is not just a regulatory box to be ticked; it is a strategic document that, when used effectively, can be a driving force in transforming a medical device concept into a market reality. As medical device companies navigate the intricate pathways of MDR 2017/745, a well-crafted clinical development plan will act as a beacon, guiding them to successful marketing approval and beyond.

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Target Product Profile

The Target Product Profile (TPP), as defined by the World Health Organization (WHO), serves as a comprehensive blueprint outlining the desired characteristics of a product targeted for a specific disease or diseases. WHO's TPPs play a crucial role in guiding research and development (R&D) efforts in various sectors. In the industry, internal TPPs function as strategic planning tools, directing development towards desired attributes. From a regulatory perspective, TPPs aid in framing development concerning the submission of product dossiers. In the realm of public health, these profiles establish R&D targets for both funders and developers. WHO's emphasis on access, equity, and affordability within TPPs ensures that the innovation process considers these integral aspects throughout development, not just post-product creation. These documents, whether specifying preferred or minimally acceptable profiles, provide valuable guidance for stakeholders, including product developers, regulatory agencies, procurement agencies, and funders. Over the past few decades, TPPs have played a pivotal role in guiding drug development.

Now, as medical device developers navigate the complex landscape of strategic planning and regulatory compliance, incorporating the lessons learned from TPPs is becoming a critical and advantageous task to ensure maximum success in their endeavours.

Author: **PD Dr. Ghazaleh Gouya-Lechner**, Member of GPMed and IFAPP Board of Officers, CEO of Gouya Insights

Exploring New and Emerging Trial Designs Considering the Revision of the Declaration of Helsinki

IFAPP is a member of the international network of the World Medical Association (WMA), and I was truly honoured to be invited as a speaker to the Regional Meeting in Europe on the Revision of the Declaration of Helsinki (DoH), which took place on September 21 and 22, 2023, at the Laegeforeningen, Danish Medical Association, in Copenhagen.

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The DoH of the WMA has provided ethical principles for medical research involving humans, including research in identifiable human material and data since 1964, with the last update in 2013.

To complement the DoH, the WMA issued the Declaration of Taipei (DoT) in 2016 to provide additional ethical principles for health databases and biobanks.

In 2022, the WMA appointed a workgroup to begin the process of revising the DoH seminal document. To encourage as much global participation in the revision process as possible, the WMA is collaborating with its members by hosting a series of regional meetings.

The WMA European Regional Meeting was co-organised by the Danish Medical Association, the American Medical Association, and the WMA.

The Laegeforeningen, Danish Medical Association building in Copenhagen (Source: https://en.wikipedia.org/wiki/Domus_Medica#Architecture)

The recent WMA Regional Meeting in Europe on the Revision of the DoH in Copenhagen provided an opportunity for organisations from the European region to hear presentations and provide input on the current draft. This event was held in person and was open to all WMA members and invited guests online.

My task as a speaker of the session “Exploring New and Emerging Trial Designs” was to share IFAPP’s real-world experience with new and emerging trial designs regarding ethical challenges from the perspective of physicians and biomedical scientists working in and with the pharmaceutical industry in view of the revision of the DoH. In essence, I had to address how the new trial designs impact research ethics and how they can be considered in the next revision of the DoH. My co-speakers, Dr. François Bompart from Inserm, addressed the experiences and challenges, particularly in the context of the VoIRE Initiative for healthy volunteers, and Dr. Otavio Berwanger, from the George Institute for Global Health and Imperial College, provided the academic perspective.

The IFAPP input and perspective were well received and appreciated during the two days of work and the exchange of opinions.
The published proposals of the IFAPP Ethics Working Group were the core of my presentation and triggered constructive discussion with the WMA members and audience (ref. 1, 2, 3, 4, 5).

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IFAPP recommended topics for the revision of Declaration of Helsinki version 2013

1. Connection of Declaration of Helsinki (DoH) & Declaration of Taipei (DoT)
2. Ethical approval & consent for secondary use of data
3. Incidental findings
4. Registration of "data sharing plan" and study results in public databases
5. Shared responsibility
6. Patient & Public involvement plan
7. Diversity of membership & qualified experience of Research Ethics Committees (REC)
8. Terminology aspects of human subjects & humans, participants, etc.
9. Medical research for common nomenclature between organisations
10. Placebo use wording & alignment of wording CIOMS & WMA (paragraph 33 DoH)
11. Vulnerable population
12. Post-trial access

The DoH is fundamentally a high-level ethical principles document and not a guidance.

The DoH workgroup will consider changes in the DoH text only if new clinical trial designs or technologies create new ethical issues. New clinical trial designs and technological developments currently shed more light on existing ethical issues than present new ones.

The nuances of the emerging new clinical trial designs and technologies' issues are anticipated to be dealt with guidelines from CIOMs that focus on the application of the principles.

The WMA will continue the dialogue in the forthcoming regional meetings and explore further views on vulnerable patients' aspects and research in resource-poor settings.

The Declaration of Helsinki and the Declaration of Taipei remain the key documents for biomedical research in humans and should be considered accordingly. IFAPP's positioning on the topic of linking these documents has been published in Front. Pharmacol., Vol. 11, October 29, 2020.

WMA will continue its efforts to sharpen the language in the DoH for better common understanding to protect the well-being and rights of patients involved in medical research and support the social value of research by promoting responsible ethical conduct of research in humans.

I would like to acknowledge the members of the IFAPP Ethics Working Group for their great efforts and recognise the major contributions of Prof. Kotone Matsuyama, BSocSc, specially appointed Prof. Chieko Kurihara, and Prof. Sandor Kerpel-Fronius in shaping the IFAPP recommendations on the DoH revision.

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Dr. Varvara Baroutsou
IFAPP President

Philippine College of Pharmaceutical Medicine: Beginnings, Transitions and Future Directions

On 26 October 2023, the IFAPP Webinar featured one of its NMAs, the Philippine College of Pharmaceutical Medicine (PCPM), with Dr Jose Rodolfo Dimaano Jr, PCPM Board Member, as speaker. He was later joined by panellists, Dr. Herbert Ho, PCPM President, Dr. Jonas Policarpio, PCPM Past President and DPMM Course Director, and Dr. Milagros Tan, PCPM Vice President. Entitled “PCPM: Beginnings, Transitions and Future Directions”, the webinar recounted the beginnings of Pharmaceutical Medicine in the Philippines and shared the evolution and journey to the organisation that it is today.

Maria Caridad P Purugganan

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The 1960s and 1970s saw the rapid growth of the pharmaceutical business and the incursion of multinational pharma companies and products, and the beginnings of PCPM was sparked in 1969 as an organisational meeting among Medical Directors in the pharmaceutical industry. It went on to forge partnerships with the Philippine Medical Association and the Ministry of Health as the Medical Directors filled the role of government liaisons, regulatory leads, product stewards and reviewer of market communications and promotional materials. More partnerships followed with involvement in Health and Pharmacology Research and Clinical Trials. The following decades went on to meet the educational needs of pharmaceutical medicine and along the way, the organisation was renamed "Philippine College of Pharmaceutical Medicine." Government regulations further encouraged the growth of the discipline through enforcement of laws that affirmed the requirement for all drug establishments to have a Medical Director and for PCPM representatives to be part of the National Pharmacovigilance Committee. One key directive that was passed into law, was the appointment of a Medical Director for companies to have a License to Operate in the Philippines and that Medical Directors should have passed the specialty board of Pharmaceutical Medicine.

At present, PCPM has more than 200 physician and non-physician members within the pharmaceutical industry. It has partnered with a major university, the Ateneo de Manila to provide a Diploma Course in Pharmaceutical Medicine, with a curriculum based on the 2018 PharmaTrain syllabus and adapted to the Philippine context.

Still, with all the PCPM initiatives and milestones achieved, more plans are on the horizon. There is the aim to grow the awareness and interest in Pharmaceutical Medicine and for Pharmaceutical Medicine to be recognised as a medical specialty. Another is the application of the Diploma Course in Pharmaceutical Medicine to PharmaTrain for course evaluation and recognition.

PCPM founders, past and present leaders and members continue to work collectively to evaluate, recalibrate and outline their roadmap as they keep up with the changing healthcare and pharmaceutical landscape, to work towards the goal of maintaining high standards of practise and professionalism in the country.

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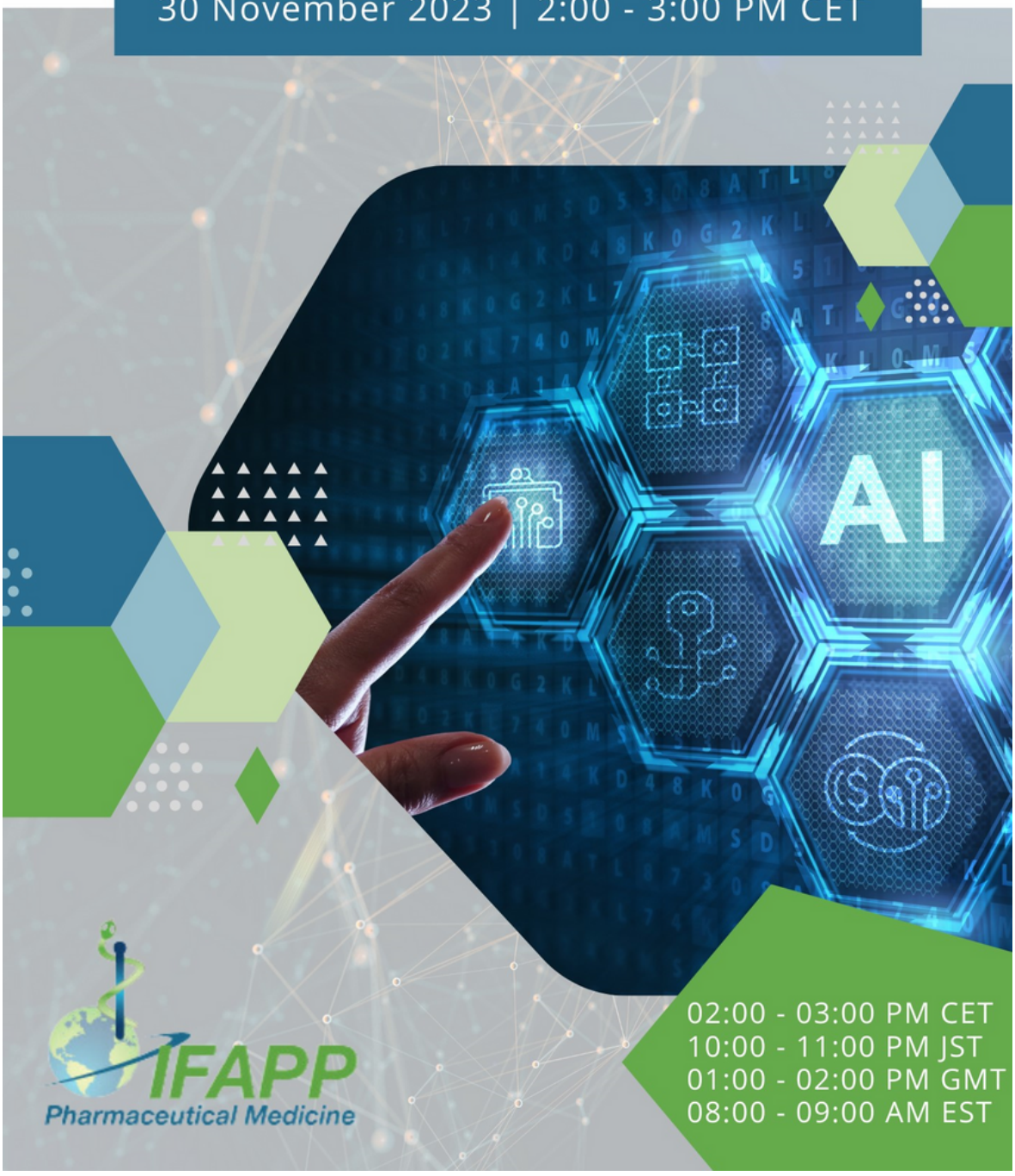

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AI IN PHARMACOVIGILANCE, EMPOWERMENT THROUGH AUTOMATION

30 November 2023 | 2:00 - 3:00 PM CET

Speaker: **Sriram Venkateswaran**,
Senior Safety Data Scientist
Safety Data Science || Safety Analytics and Reporting
Safety and Risk Management, Product Development
F. Hoffmann-La Roche Ltd.

You are invited to a Zoom webinar.
When: Thursday, November 30, 2023 02:00 - 03:00 PM CET
Topic: AI in Pharmacovigilance, Empowerment through Automation

Register in advance for this webinar:

https://us02web.zoom.us/webinar/register/WN_3vKoToTlQvqhEODfVpudKg#/registration

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

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

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