IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

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Introducing IFAPP President-Elect Eric Klaver

It is with pride that I received the honour by the House of Delegates to be elected to the position of President-Elect of IFAPP last December. With a lot of enjoyment have I taken place in the current Board, and I’m looking forward to learning a lot from Varvara, our current president, and also still from Marco, our past-president.

Before sharing a bit about my background, the history, I’d like to start by looking at the future. As that is where my focus typically lies. Learn from the past, but focus on the future.

During her presidency I’m watching Varvara Baroutsou working hard to rejuvenate IFAPP. Ensure its continued relevancy and setting it up for the successful continuation in the years to come.

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I admire her sound and solid leadership, and will certainly benefit from that, in my preparation to follow her and during my coming presidency. Of course, we never know where the future will bring us. But as the philosopher Michel de Montaigne said: 'No wind favours he who has no destined port'. So let's look ahead and see which port our ship should be heading to.

I'm happy to have some time, as president-elect, to look at many different directions that are available for a federation as the IFAPP. And I'm lucky to come in at a time when the foundation of the federation is solid. So we have opportunities to build. With my mindset of today, I'm looking forward to working with the member associations to make sure that the federation benefits the associations in the best way possible. At the same time, with a relevant, solid federation, there is opportunity to grow. I hope to work towards adding further associations to our federation, increasing our relevance in the overall field of Pharmaceutical Medicine. And those who know me will not be surprised to learn that a common focus of mine is on increased diversity. Anywhere. In our own representatives, in our trial populations, in our memberships, all aspects of Pharmaceutical Medicine.

I'm known to be an out and proud activist working on social justice and I don't shy away from putting the finger on the sore spots. With that comes my Dutch blunt communication style. It's a well-known fact that subtlety and me have not become good friends. Diplomacy and me, however, walk hand in hand. Working with me, you'll know where I stand. I excel at agreeing to disagree, but just as much as I want people's opinions heard, I'll share mine alongside. Only that way, we can come to grow and build on each other's insights.

For those who'd like to know more about my background, I'll share the Cliffs Notes version. Feel free to peruse my LinkedIn profile at your leisure for more details.

I'm an almost 55-year-old Dutchman, living in Amsterdam with my husband and 2 wonderful dogs. I started working in the field of Pharmaceutical Medicine in 1994, so that make this year a 30-year mark. I've worked in a host of roles, from Data Management to Medical Advisor, spent most of the years (20+) training Clinical Research, and I still teach the master module 'Clinical Development & Clinical Trials' at the Amsterdam VU University each year. Conveying the message that products should be developed with the highest possible ethical and scientific standards, with a strong eye on equity, has been the focus of my career. I've learned a lot from those I've been fortunate enough to train, around the world. And I've learned a lot from the work as an auditor for 8 years. Within my current role at IQVIA, my focus is on Information Governance and Privacy, adding yet another field of this magnificent world of Pharmaceutical Medicine to my experience.

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I'm an experienced board member. I'm currently serving on 6 boards, varying from a musical group, to home owners association, to being the vice-chair of the NVFG, the Dutch member association to IFAPP. And now, of course, on the board of IFAPP. A role I fulfil with pride, and determination. A determination to work with purpose to a better future. For our Member Associations and Individual Members, for the Federation, for Pharmaceutical Medicine, and for the patients who need our work so badly.

I hope to meet a lot of you at ICPM 2024, in my hometown of Amsterdam, 18-20 September this year.
Until then, warm regards,

Eric Klaver

In Memoriam: Dr Dimitrios Michailidis 1944-2024

On the 31st of January 2024, Dimitrios Michailidis, an excellent friend and colleague passed away after a long and dignified struggle with his health, without ever losing his optimism, his fighting spirit, his thirst to participate in scientific developments, his interest in the Hellenic Society of Pharmaceutical Medicine, EL.E.F.I., and his willingness to support colleagues and friends. Those of us who were fortunate enough to work with him will remember him with great affection.

Dimitrios was born and raised in the Ampelokipi neighbourhood of the post-second world war Athens, with his father's roots in Constantinople, from where he settled as a refugee in Thessaloniki in 1922. His mother, born in Herakleia in Eastern Thrace (now Marmara Ereğlisi), settled in Thessaloniki in 1914.

Dimitrios studied medicine at the National and Kapodistrian University of Athens and completed his surgical residency at the Laiko Hospital in Athens, where he developed an interest in clinical research, actively participating with key investigators in many of the pioneering research activities of the hospital at the time. He continued his residency in the United Kingdom, specialising in vascular surgery and working at London's Mount Vernon and Northwick Hospitals and Birmingham Hospital.

Returning to Athens, he fulfilled his military obligations as a medical officer in the Greek Air Force.

He then worked as a vascular surgeon at the Athens General Hospital "Elpis" and at the Athens NMTs Army Hospital. He then continued his medical practice in the private healthcare sector, while working in parallel as medical director for the pharmaceutical industry, Janssen and Upjohn.
After his retirement he donated his medical practice equipment to the Polyclinic of the Municipality of Cholargos in Athens, where he volunteered for his medical services, which had to be interrupted during the outbreak of the COVID-19 pandemic.

Most of us met him in the field of clinical trials in the pharmaceutical industry. As a medical director, he focused on clinical trials and regulatory affairs. He supported the clinical development of ketoconazole, itraconazole, cisapride, risperidone, and erythropoietin drugs that were approved

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by the National Organisation for Medicines - EOF, with Greek double-blind multicentre studies designed and conducted in the "pre-GCP" era as required then, under the Greek legislation of 1984.

Dimitrios was also Editor-in-Chief (1996-2008) of the Greek edition of the British Medical Journal (BMJ) and of the Thorax Journal (2008-2010).
He was an active member of the Greek Society of Pharmacology and the EL.E.F.I. Hellenic Society of Pharmaceutical Medicine, and until the end of his life he continued to volunteer his services to events related to medical research and scientific development in Greece.
He was always interested in the "community". From his student days, in 1965, he was a member of the Greek Medical Students' Committee, elected President in 1968 and led the Student Exchange Programme (the forerunner of today's Erasmus), increasing its membership from 120 to more than 600 students then.

Always with his horizons open, he "looked ahead". Thus, in 1991, he conceived the idea of the EL.E.F.I., which he cultivated with other colleagues, leading to its creation in December 1991. He was President of the EL.E.F.I. from 2000 to 2010 and, during his EL.E.F.I. presidency, he established contact with IFAPP as IFAPP Executive Board member and continued to be in touch with IFAPP colleagues thereafter.

Always active, even during the period of serious health problems, he was interested in the growth and development of the EL.E.F.I. Hellenic Society of Pharmaceutical Medicine, moderated trainings and seminars for EL.E.F.I. members and participated in every way in all events. He will be remembered by all of us for his integrity and fairness, his ethos and dedication to whatever he was involved in.

He was also very active in his interests and social life. As a very young scout he had attended
two world jamborees. He loved classical music, theatre, films, travelling and skiing.

Most importantly, he was not only a colleague but also a friend to many of us. A very warm and loving friend, who was always interested in our joys and sorrows.

His loss has deeply saddened us, and his presence will remain vivid in our memories. His work and contribution will always accompany EL.E.F.I. We can only express our deepest condolences to his beloved daughter Maria, his family and all his loved ones.

On behalf of EL.E.F.I.:

Eleni Anthopoulou, Christos Eleftheriou, Paschalis Tsitsios, Grigorios Rombopoulos, Varvara Baroutsou

New Leadership, New Horizons: Meet the Dynamic Board of Directors at the Helm of the Brazilian Society of Pharmaceutical Medicine

In a significant development for the Brazilian Society of Pharmaceutical Medicine (SBMF), a distinguished group of professionals has taken the reins, promising a new era of leadership and innovation in the field. Let's delve into the programme and profiles of the key figures who now compose the executive team, steering the 52-year-old society towards greater heights.

President: **Dr. Wellington Briques** - BioPharma Consulting: Dr. Briques brings a wealth of experience from BioPharma Consulting and his extensive career at global pharmaceutical companies, contributing strategic insights that promise to shape the society's vision. His leadership is anti-

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cipated to chart a course for enhanced collaboration and advancements in Pharmaceutical Medicine.

Vice-President: **Dr. Stevin Zung** – Aché: Hailing from Aché Laboratories, Dr. Zung's appointment as Vice-President signifies a commitment to excellence. His expertise in pharmaceuticals is expected to bolster the society's efforts in fostering research and development within the industry.

Secretary General: **Dr. Marcelo Vianna de Lima** - Blau Pharmaceutics: Dr. Marcelo Lima from Blau Pharma takes on the crucial role of Secretary General. His organisational acumen is poised to streamline communication and facilitate efficient decision-making, contributing to the society's overall effectiveness.

Secretary Adjunct: **Dr. Franco Martins** – GSK: Dr. Martins assumes the role of Secretary Adjunct, bringing a global perspective to the table. His involvement is anticipated to strengthen international partnerships and align the society with global pharmaceutical trends.

Treasurer: **Dr. Julio Cesar Saldanha**: As Treasurer, Dr. Saldanha is entrusted with managing the society's financial affairs. His financial expertise is crucial for ensuring fiscal responsibility and sustainable growth within the pharmaceutical physicians' community.

Treasurer Adjunct: **Dr. Ricardo Macarine Ferreira** – Pfizer: Dr. Ferreira, representing Pfizer, assumes the role of Treasurer Adjunct. His experience in the pharmaceutical giant is poised to contribute to the society's financial stability and investment in impactful initiatives.

Director of Institutional Affairs: **Dr. Helio Guy Osmo**: Dr. Osmo, past SBMF president, is appointed as the Director of Institutional Affairs, bringing a focus on the societal impact of pharmaceutical practices. His role is pivotal in enhancing the society's standing and advocacy in the broader healthcare landscape.

Scientific Director: **Dr. Elisama Queiroz** – GSK: Dr. Queiroz takes charge as the Scientific Director, emphasising the importance of cutting-edge research. Her energetic leadership is set to drive scientific advancements, fostering an environment of continuous learning and innovation.

The diverse backgrounds and expertise of these accomplished professionals reflect a commitment to a collaborative and forward-thinking approach. Their collective vision is expected to redefine the Brazilian Society of Pharmaceutical Medicine, making it a hub for innovation, research, and advocacy in the dynamic landscape of pharmaceutical medicine. As the society charts its course under this new leadership, the future holds great promise for advancements that will benefit both the profession and the broader community.

Activities Proposal

In a groundbreaking turn of events, the Brazilian Society of Pharmaceutical Medicine welcomes its new President, Dr. Wellington Briques, alongside a dynamic Board of Directors with a transformative vision for the future. Let's delve into the innovative development proposals outlined by Dr. Briques, set to redefine the landscape of Pharmaceutical Medicine in Brazil.

Innovations in Clinical Research - Driven by a commitment to expedite drug development, the board proposes exploring novel approaches and cutting-edge technologies in clinical trials.

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SBMF Annual Congress. Always packed.

This initiative aims to revolutionise the research landscape, accelerating the pace of bringing innovative drugs to market.

Development of Medicines for Rare Diseases - Focusing on the unique challenges within the Brazilian context, the board aims to strategise and overcome obstacles in researching and developing medicines for rare diseases. This proposal underscores the commitment to inclusivity in healthcare and addressing unmet medical needs.

Personalised Medicine and Precision Therapies - The board recognises the transformative potential of personalised medicine. Dr. Briques advocates exploring the latest trends and the pivotal role precision therapies play in reshaping clinical practices, offering tailored treatments for individual patients.

Regulation and Compliance in the Pharmaceutical Industry - To ensure the industry's integrity, the board aims to provide regular updates on national and international regulations. Emphasising compliance practices, this proposal aims to foster a transparent and ethically sound pharmaceutical environment.

Communication Strategies in Pharmaceutical Medicine - Effective communication is pivotal in healthcare. The board proposes strategies fostering collaboration between healthcare professionals, the pharmaceutical industry, and patients. This initiative aims to enhance transparency and understanding among stakeholders.

Ethical Challenges in Clinical Research - Recognising the evolving ethical landscape, the board commits to reflecting on emerging ethical issues in clinical research. This proposal aims to ensure that ethical considerations remain at the forefront of drug development and clinical studies.

Health Technology Assessment (HTA) in the Brazilian Context - Dr. Briques and the board envision practical applications of HTA in health decision-making in Brazil. This includes, among others, cost-effectiveness analyses that can inform policy and contribute to a sustainable and efficient healthcare system.

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SBMF is highly respected for its educational events.

Trends in Pharmaceutical Medicine in Latin America - The board emphasises regional collaboration by sharing experiences and discussing the latest trends and challenges in Pharmaceutical Medicine throughout Latin America. This proposal aims to foster a unified approach to common issues in the region.

Artificial Intelligence and Clinical Development
a) Impact of Artificial Intelligence on Pharmaceutical Research - Exploring how artificial intelligence transforms the discovery of medicines, diagnoses, and treatments.
b) Artificial Intelligence in Drug Discovery - Examining how AI algorithms accelerate the identification of promising molecules, optimising the process of discovering new drugs.
c) Machine Learning Applications in Clinical Research - Discussing the use of machine learning to improve participant selection, predict clinical trial results, and personalize treatments.

As the Brazilian Society of Pharmaceutical Medicine steps into this new era under Dr. Wellington Briques' leadership, the outlined proposals sign a commitment to pioneer advancements, ethical standards, and collaborative efforts that will undoubtedly shape the future of Pharmaceutical Medicine in Brazil and beyond.

Authors:
All **SBMF board members** as described above.

Dr. Wellington Briques,
SBMF President

Analysis of the EMA Guidance “Guideline on computerised systems and electronic data in clinical trials”

The Italian Group of Quality Assurance in Research (GIQAR), part of the Italian Society of Pharmaceutical Medicine (SIMeF), undertook an analysis on the final guideline issued by the European Medicines Agency (EMA) on “Computerised systems and electronic data in clinical trials”. This guideline, which officially came into effect in September 2023, expresses the current thinking of the GCP inspectors on the digitisation and modernisation that has deeply changed the context of clinical research processes in recent years.

The key focus of the guideline is ensuring the integrity and reliability of data in a clinical landscape increasingly characterised by digital methodologies. Validating computerised systems across their entire lifecycle, with emphasis on the principles of GCP and appropriately declined ALCOA++ requirements, should ensure reliability and regulatory acceptance of electronic data in clinical trials.

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We summarised the guideline in nine points of interest: new computerised systems in scope, reinforcing the concept of data, extent and responsibilities for computerised system validation, electronic data transmission and e-source data identification, control of data and management of dynamic data, audit trail and audit trail review, training, management of computerised systems at clinical sites (please check the full-article linked in this page for a detailed description).

The new guideline provides directions to sponsors, CROs, investigators, and other parties involved in the design, conduct and reporting of clinical trials on the management of computerised systems and clinical data. It does not technically introduce new concepts, but finally clarifies inspectors' expectations on several compliance areas: it provides a fresh and modern view on new and emerging technologies (e.g., wearables, cloud) and establishes a solid ground to support and reinforce service providers and sites compliance.

Some of the requests pose significant challenges particularly for ongoing clinical trials. One example is the demanding requirement to retain data preserving their dynamic state. Implementing this effectively will require considerable effort, especially for trials already underway. Additionally, some requirements could be particularly complex for clinical sites as they may necessitate entirely new data management approaches.

Given the increasing prevalence of electronic systems in clinical research, complying with these new compliance challenges, is imperative. Collaborative efforts between researchers, regulatory bodies and technology providers are crucial to develop and implement effective and efficient solutions that meet these requirements.

Link to the full article, Il Giornale della SIMeF Number 5-2023.

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Massimo Tomasello: GCP/GLP Senior Specialist and Auditor (CHIESI FARMACEUTICI S.p.A)

GIQAR GCP working group on computerised systems in clinical trials.

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Unlocking the Future: IFAPP Webinar Explores the Promise of Cell Therapy in Medicine

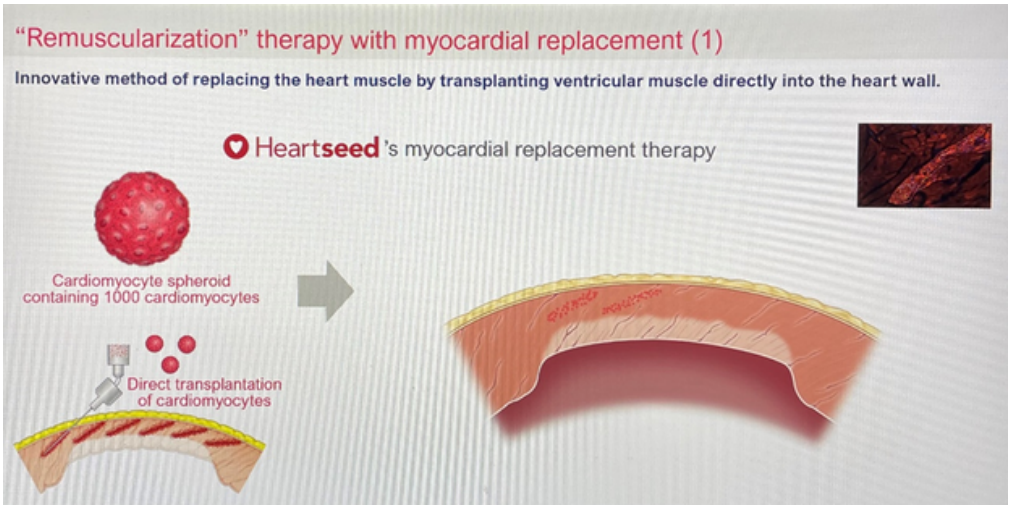
In the realm of medical breakthroughs, few topics hold as much promise and fascination as cell therapy. This was the focal point of a recent IFAPP webinar that brought together leading experts and enthusiastic learners to delve into the latest advancements and challenges in this rapidly evolving field.

Organised by the IFAPP Education and Certification Working Group (ECWG), the webinar was conducted on 29 February 2024 by inviting an impressive speaker, Dr. Takehiko Kaneko. Dr. Kaneko, Chief Medical Officer at Heartseed, brought a wealth of various experiences including big pharma and venture companies. His keynote address, titled "The New Era of Cell Therapy: Innovative Approaches from Production to Commercialization," paved the way for an insightful exploration into the intricacies of this revolutionary medical frontier.

Accompanying Dr. Kaneko was the esteemed Dr. Andras Dinnyes, a distinguished professor celebrated for his contributions to embryology, cloning, and stem cell biology. Dr. Dinnyes, serving as the panel moderator, adeptly guided the discussions, drawing from decades of pioneering work to provide invaluable insights into the complexities of cell therapy.

The panel examined a range of pressing topics, each shedding light on different aspects of cell therapy:

Quality Assurance Challenges and Solutions: Dr. Dinnyes and Dr. Kaneko discussed the unique challenges in ensuring the safety and effectiveness of cell-based therapies. From manufacturing to delivery, they explored rigorous quality assurance measures and emerging standards aimed at meeting these demands.
Regulatory Landscape: Navigating the regulatory landscape for cell therapies can be daunting, especially with its unique complexities. Dr. Kaneko and Dr. Dinnyes offered insights into the current regulatory framework, emphasising the need for adaptable approaches to accommodate the novel aspects of these treatments.



Cell therapy developing by Heartseed

Patient Access and Reimbursement Models: Economic considerations play a crucial role in the accessibility of cell therapy. Dr. Kaneko highlighted innovative reimbursement models aimed at ensuring broader access to these transformative treatments. Discussions centred on striking a balance between affordability and sustainability, critical for equitable healthcare.

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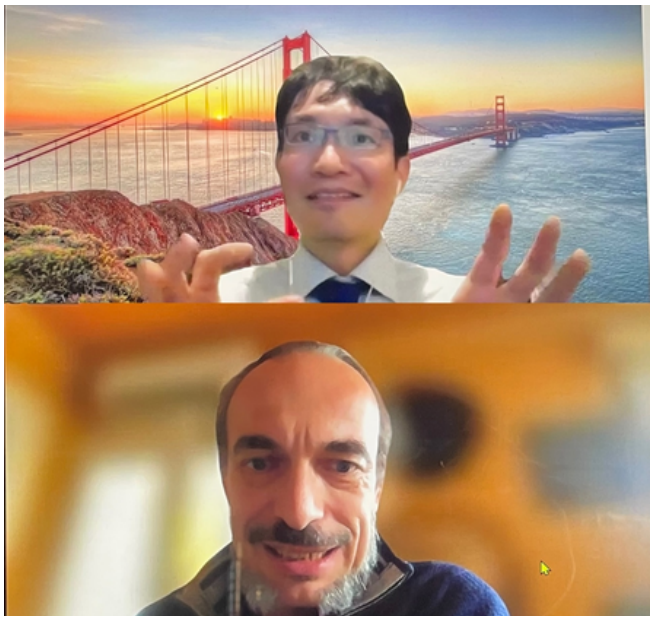

Dr. Takehiko Kaneko and Dr. Andras Dinnyes

As the webinar concluded, participants gained a deeper understanding of the transformative potential of cell therapy. The convergence of scientific expertise, regulatory insights, and economic considerations painted a compelling picture of a future where debilitating diseases could one day be conquered through regenerative medicine.

In the aftermath of this enlightening webinar, one thing became abundantly clear: the journey towards realising the full potential of cell therapy has only just begun. With each step forward, we edge closer to a future where medical breakthroughs are not just aspirations, but tangible realities awaiting discovery.

Author:
Shinichi Nishiuma, MD (IFAPP ECWG)

Building PBPK Capabilities in Africa: #PBPK2024

The #PBPK2024 workshop was the result of a partnership between the Maternal and Infant Lactation pharmacoKinetics (MILK) programme led by Professor Catriona Waitt from the University of Liverpool (UoL) and the Infectious Diseases Institute, Makerere University (IDI), and Professor Saskia de Wildt from Radboud University Medical School (RUMC), both of whom are current beneficiaries of funding from the Bill & Melinda Gates Foundation with specific objectives to increase the application of physiologically-based pharmacokinetic (PBPK) modelling to global health challenges. #PBPK2024 was hosted by the IDI in partnership with RUMC and other global partners to provide hands-on demonstration of the application of PBPK modelling. The goal was to bridge the gap between PBPK modelling specialists and decision-makers in global drug development and clinical care, in order to increase awareness of the technique with specific reference to the global health challenges affecting our populations. Pregnant and breastfeeding women and children often face challenges in pharmacotherapy due to limited dosing information. PBPK models, validated with clinical data, offer a promising solution, by integrating the underlying physiology related to pregnancy, lactation and foetal growth and development to establish population-specific dosing. While PBPK modelling is increasingly used in drug development, its application in addressing dosing questions for pregnant and lactating women and children is a relatively new area of application and this was the focus of the workshop.

The workshop brought together 65 delegates and 11 tutors from countries including: Uganda, Kenya, Tanzania, Zimbabwe, Nigeria, DR Congo, South Africa, Netherlands, Switzerland, France, UK, and USA. Tutors from RUMC (Rick Greupink, Joyce van der Heijden, Charlotte Koldeweij) and SimCyp (Karen Rowland Yeo, Lisa Almond, Amita Pansari and Kelly Turton) were joined by Shakir Atoyebi, PhD student at UoL. Delegates included senior clinical pharmacologists, clinical pharmacists, physicians and investigators from across Africa, as well as members from the Ugandan National Drug Authority. The regulatory perspective on PBPK was covered by representatives from the UK

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Medicines and Healthcare Products Regulatory Agency (Essam Kerwash and Andrew Butler). Specific to the question of antimalarial use in pregnancy and breastfeeding, collaborators from the Medicines for Malaria Venture, Myriam El Gaaloul and Sonia Khier brought their expertise. Ping Zhao, Senior Project Officer from the Bill & Melinda Gate Foundation provided hands-on tuition and was supported by Jacqueline Bryan, Business Manager.

Hand-on simulation scenarios

Delegates delved into the fundamentals of PBPK modelling, exploring its impact on drug development and considering crucial factors when applying these models to evaluate drug dosing in specific understudied populations. Through interactive simulations, delegates gained practical experience using PBPK models to assess the impact of physiological changes on drug disposition. Discussions revolved around establishing the necessary framework for incorporating simulation-based evidence to inform optimal drug use. The workshop addressed regulatory aspects of PBPK modelling, providing insights into its integration into the drug development and approval process. A guided tour through clinical, research and laboratory facilities at IDI enabled delegates to place their learning in context, and to interact with different study teams which we hope will foster growth of the collaborative network.

The workshop marked the first dedicated PBPK event in East Africa, laying a strong foundation for future collaborations and growth in the region. Delegates recognised the critical need to use PBPK models for addressing complex questions related to dose selection in traditionally underserved populations. All left with hands-on experience of using the software, with an appreciation of how to apply this knowledge in real-life scenarios.

The delegates were also treated to a Ugandan cultural extravaganza by way of a social evening filled with traditional folk dance, music, comedy and food, which enabled further networking and an opportunity for those new to Uganda to understand more about the context and culture.

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In conclusion, the #PBPK2024 workshop in Kampala was a catalyst for change, offering a promising avenue to optimise drug therapy for the most complex and understudied populations.

Authors

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Conference photograph, Ndere Cultural Centre

Illustrations courtesy of Tabu Studios

Meeting with PhD Candidates

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TIMETABLE IFAPP WEBINARS 2024

24 April 2024

2 pm – 3.30 pm CET

PharmaTrain Syllabus Update (new version – revision 3)

Speaker: Prof. Peter Stonier

Panelists: to be confirmed

29 May 2024

11 am – 1 pm CET

CAR T Cells and Ethical Aspects (patients' involvement)

Speaker: Dr. Antonio Perez Martinez from the University Hospital La Paz, Madrid

Panelist: Dr. Karin Blumer (BMS)

List of webinars proposed

June 2024

CTR Update – 6 months left for adaptation to new regulation

October 2024

AI and Pharmacovigilance

November 2024

The European Young Persons Advisory Group Network (eYPAGnet)

Speaker: Begonya Nafria

Panelist: to be confirmed

December 2024

Declaration of Helsinki

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

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