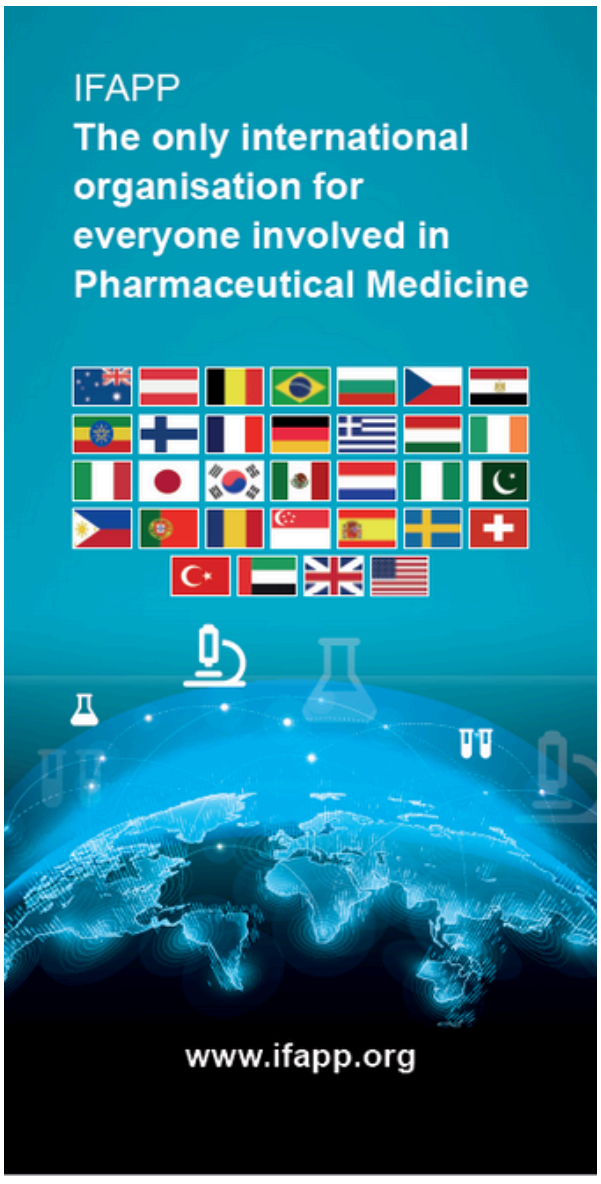
IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE



THIS ISSUE INCLUDES:

A Word from the New President, Eric Klaver

(adapted from his speech at the conclusion of ICPM 2025 in Amsterdam)

Good afternoon, colleagues and friends,

It was truly an honour to stand before you, at the conclusion of the inspiring ICPM 2025 conference and at the beginning of my term as President of IFAPP.

The theme of this year's conference, "Purpose for Future", could not have been more fitting. It captured not only the challenges ahead of us, but also the opportunities. We all gathered in Amsterdam because we believe in the future of Pharmaceutical Medicine. And we want that future to be meaningful, sustainable, and shared.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Before speaking about the path ahead, I will take a moment to express my sincere gratitude to two people whose leadership has brought us to this point:

- First, to Dr Marco Romano, our Immediate Past President. Although he was not present with us, I want to thank him on behalf of the entire IFAPP community. Marco officially stepped down from the IFAPP Board now, and, with that, we mark the close of an important chapter. His commitment, vision, and service have left a lasting impact on this Federation, and his steady guidance through times of transition has positioned us well for what will come next.

- And to Dr Varvara (Barbara) Baroutsou, whose term as President has now officially come to a close. Thank you, Varvara. Your leadership has been defined by clarity, professionalism, and passion for IFAPP's mission. I am personally grateful that you will continue on the Board as Immediate Past President, and I look forward to continuing our collaboration in this new capacity.

Let me now turn to a short personal note.

As some of you may know, I am the first person to serve as IFAPP President who is not an MD, not a physician. I am, however, medically trained, and I have worked for many years in Pharmaceutical Medicine across research, development, ethics, and policy. But I see my background not as an exception, but as a reflection of where our field is going.

Pharmaceutical Medicine is no longer defined by a single profession. It is a collaborative, multidisciplinary space. We are scientists, pharmacists, ethicists, clinical operations leaders, regulatory experts, data scientists, and yes, physicians, all working together to ensure that safe, ethical, and effective medicines reach patients.

I believe IFAPP must reflect and celebrate this diversity because our strength as a Federation lies in our broadening the perspectives we bring, the disciplines we connect, and the shared purpose that unites us. And that brings me to why I am here today, not just to begin a role, but to begin a journey.

As I take on this responsibility, I want to focus on two connected goals:

- First, I want to increase awareness of what IFAPP is, what it offers, and why membership matters among our National Member Associations, our Individual Affiliates, and those outside our Federation who should know who we are.

- Second, I want to increase the value of that membership not just by highlighting what we already do, but by expanding it, strengthening it, and making it even more relevant, practical, and future-focused. I believe the best way to begin is simple: by listening.

In the first six months of my term, I will be speaking with the presidents of each of our NMAs. I want to understand your local priorities, your members' needs, your visions for how IFAPP can help. These conversations will shape everything we do next. Because IFAPP is a Federation. That means we are not one voice, we are many voices, coming together. And the more clearly we listen to each other, the stronger we will be.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Now, based on what we already know, there are three major priorities I want to begin working on immediately:

- **First: Modernisation**

We need to ensure that IFAPP's tools, platforms, and ways of working are modern and user-friendly. We want it to be easy for members to engage, contribute, and benefit. Whether it is through virtual events, educational content, or collaboration spaces we must evolve with the times.

- **Second: Visibility**

We have amazing working groups, initiatives, and expertise across IFAPP. But we need to tell that story both internally and externally. We want our members to feel proud and connected. And we want the outside world, industry, regulators, academia, and patient organisations to recognise IFAPP as the global voice of Pharmaceutical Medicine. One of the most effective tools we already have in this area is IFAPP TODAY, our digital magazine. It plays a vital role in showcasing the work being done across the Federation from scientific updates to member news and expert interviews. I want to express my deep appreciation to everyone involved in its creation. It is a valuable voice for our community, and we will continue to support and grow its reach.

- **Third: Value**

This is the heart of it. What do members gain from being part of IFAPP? How can we offer more training opportunities, more networking, more influence on policy and science? How do we make sure that being part of this Federation advances careers and strengthens local efforts? These are not just administrative tasks. They are acts of purpose. Because if we want IFAPP to be ready for the future, we must first be clear about why we exist. And then we must act on that purpose with intention, with clarity, and with commitment.

I believe deeply in this community. I believe in our potential. And I believe that, together, we can shape a Federation that not only adapts to the future but defines it.

- A Federation that embraces the full diversity of our field.
- A Federation that speaks with authority and acts with integrity.
- A Federation that is known, valued, and trusted across the world.

So, to the General Assembly and to all the members who make this Federation what it is I want to say, "Thank you". Thank you for your trust. Thank you for your dedication. And thank you for allowing me the privilege to serve.

Let us build this future together, with purpose, and for the future.

Eric Klaver
President IFAPP

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

ICPM 2025 – Purpose for Future in Pharmaceutical Medicine

What an extraordinary gathering in Amsterdam!

ICPM2025 brought together global experts, regulators, academics, patient advocates, and industry leaders to shape the future of Pharmaceutical Medicine. From cutting-edge science to ethics, from Artificial Intelligence (AI) and genomics to regulatory harmonisation – this was purpose-driven progress in action.

Highlights that inspired us:

- Ethical leadership and patient voices at the centre
- Genomics, mRNA, AI, and wearable tech redefining R&D
- A call for faster and smarter clinical trials in Europe through ACT EU
- Medical Affairs 2.0 and the future of meaningful scientific exchange
- Pharmacogenetics, HTA innovation, and Real-world Evidence as tomorrow's gold standard

And beyond the sessions?

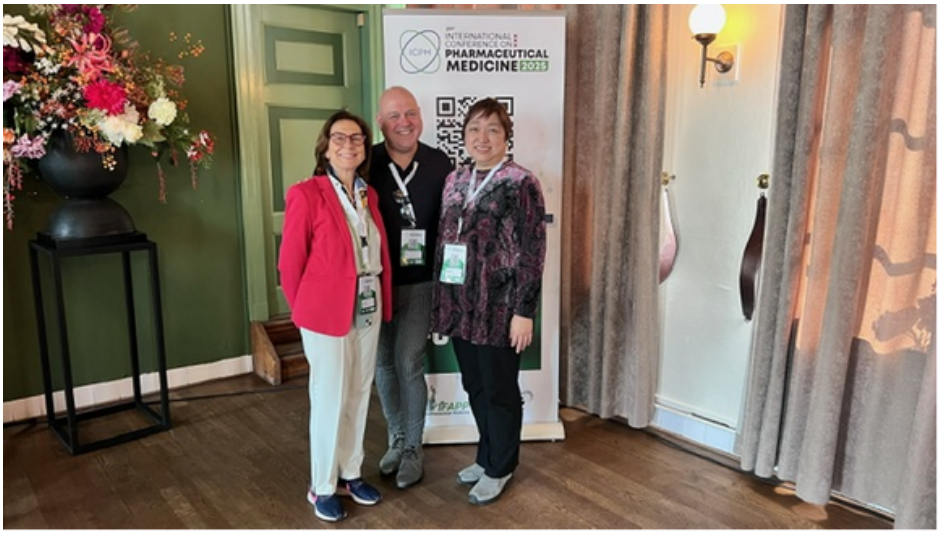
Unforgettable networking, brilliant poster presentations, and the joy of reconnecting with the global IFAPP and NVFG community, all in the historic setting of the West-Indisch Huis in the heart of Amsterdam.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

A heartfelt thank you to the organisers, speakers, and participants who made this a true success. We leave recharged, challenged, and connected – and we can't wait to see you all again in two years!

Author:
Ghazaleh Gouya, Chair of the Communication Working Group of IFAPP

Eric Klaver, President, and Ghazaleh Gouya, Chair of Communicaton WG



Varvara Baroutsou, Past-President - Eric Klaver. President - Kotone Matsuyama, President-Elect

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

IFAPP Pharmaceutical Medicine

IFAPP Pharmaceutical Medicine

IFAPP first combi-webinar
ICH - GCP E6 (R3)

€ 50,00

Dates:

- 30 June 2025
- 18 September 2025

Time schedule

18 June

04.00-06.00 AM EST
09.00-11.00 AM GMT
11.00-01:00 PM CEST
06.00-08.00 PM JST

ICH – GCP Revision

18 September

03.30-08.00 AM EST
08.30-01.00 PM GMT
10:30-03:00 PM CEST
05.30-10.00 PM JST

Good Clinical Practice (GCP) is the international scientific and ethical standard for the conduct of interventional clinical trials. The ICH E6 Guideline, published in the mid-1990s, established a harmonised understanding of GCP.

New trial designs, new technology and the greater use of different data sources required a comprehensive revision of the guideline. This seminar will familiarise participants with the key aspects of this revision.

Leidsestraatweg 41D Woerden, Netherlands

www.ifapp.org

secretariat@ifapp.org

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

IFAPP WEBINAR

ICH – GCP Revision

As already announced IFAPP will hold a unique "combi-webinar" on two occasions:

- on **30th June 2025** from 11:00 am CEST to 1 pm CEST (to note: new time slot) and
- on **18th September 2025** from 10:30 am CEST to 3:00 pm CEST.

This combi-webinar will allow the audience to learn from the top experts about the new ICH-GCP E6 Rev. 3 and to ask questions or to express doubts about its implementation.

The first part of the combi-webinar on 30th June 2025 focuses on basic information:

ICH-GCP E6 revision 3: Background, changes and Q&A.

First-hand information will be provided by **Gabriele Schwarz** and **Rebecca Stanbrook**. This webinar will familiarise participants with the key aspects of the revision.

The second part of the combi-webinar on 18th September 2025 will supply hands-on information :

ICH-GCP: Practical challenges of implementing ICH-GCP Rev. 3 in your clinical trials.

What to do, how and when. Recommendations will be provided by **Ingrid Klingmann** and **Elisabeth Reus**.

Registration fee for the combi-webinar: € 50.00

Register for this webinar

AFTER REGISTERING, YOU WILL RECEIVE A CONFIRMATION EMAIL CONTAINING INFORMATION ABOUT JOINING THE WEBINAR.

Leidsestraatweg 41D Woerden, Netherlands | www.ifapp.org | secretariat@ifapp.org

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

Summary of the Webinar of 6 May 2025:

Ethics in Data-driven Research:
WMA Declaration of Taipei on Health Databases and Biobanks
Part 1: Introduction and future direction

The speakers were

- **Dr Jón Snædal**, Icelandic Medical Association (WMA), Chair of the Working Group for the 2016 Declaration of Taipei
- **Dr Miguel Roberto Jorge**, WMA President (2019-2020)
- **Dr Otmar Kloiber**, Secretary WMA

IFAPP organised this webinar as members had been continuously stressing the importance of the Declaration of Taipei (DoT), 2016 (1, 2) which was included in the Declaration of Helsinki (DoH) 2024 amendment (3).

Dr Jón Snædal gave an introduction on how ethics related to data-driven research have been discussed in the WMA and the process of development of the DoT.

The DoT starts by aligning itself to the DoH. In the first paragraph it states that the DoH lays down ethical principles for medical research involving human participants, “including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological material and data.”

And then it specifies its own aims (paragraph 3):
“This Declaration of Taipei is intended to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients.”

Some key principles cover:

- identifiable data/material, central ethical principles, consent, multiple and indefinite use,
- information to give to those who have “given” data or material,
- the rights of individuals, and
- intellectual property, governance.

Dr Snædal closed the presentation with the statement, “To establish an ethical framework for the use of health data and biomaterial is an everlasting challenge. Health data are not only kept in ever increasing repositories, artificial (augmented) intelligence is adding a new dimension to the challenge”.

Furthermore, information on the health of individuals is not only kept in databases inside the health service but is increasingly collected into commercial repositories, sometimes of gigantic sizes. However, knowledge created using the use of big data is benefiting individuals and societies but how to handle this in an ethical way needs to be stipulated by respected institutions.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The World Medical Association is very trusted and in fact an authority in medical ethics and should be leading on how to use health data and biomaterial in an ethical way.

Dr Miguel Roberto Jorge presented the DoT:

- The WMA DoT intends to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients.
- Its main ethical principle respects the dignity, autonomy, privacy and confidentiality of individuals entitled to exercise control of the use of their personal data and biological material.
- If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the WMA DoH.
- But, if the data and biological material are collected and stored in a Health Database or a Biobank for multiple and indefinite uses, consent is only valid if the concerned individuals have been adequately informed about a series of criteria that includes their individual rights as well as the governance of the Health Database or Biobank.

Dr Jorge pointed out that the WMA DoT was created in 2002 and revised just once in 2016 before the appearance and/or its widespread use in social media, mega studies/big data and artificial intelligence.

When considering ethical aspects of research using new technologies such as social media, big data, artificial intelligence, the most discussed ethical issue is that the current model of informed consent usually is not suitable. Other important issues to be ethically considered involve public data not intended for research (from social media sources), re-use of data not originally collected for research purposes (from big data collections), and the potential re-identification of anonymised data (using artificial intelligence).

Dr Jorge concluded his presentation with a reference to Friesen at al 2021 (4), “With people increasingly recording and uploading details of their daily lives to cloud-based applications, that is, to those accessed over the internet, personal health data can now be inferred from non-medical data points, such as social media posts and browsing histories, or collected from consumer devices such as fitness trackers and smart speakers. From this data abundance, researchers build databases and train machine learning algorithms to predict, diagnose, and classify those whose data have been collected. This novel ability to create health data from unrelated online content has been called ‘emergent medical data’ and often takes place without the awareness or consent of users.”

Dr Otmar Kloiber pointed out that the DoH is a living document which has to be adapted according to changes in science.

The most important change in the 2024 DoH, mentioned by all three speakers, is the change of the key term from “research subject” to “research participant”. For this reason, except in the context of mentioning some historical documents etc., the term “participant” and NOT “subject” should be used.
This has also been taken into account in the ICH-GCP(R3) (5).

Dr Kloiber raised the questions, *Isn’t the DoH enough protection? Will the key protections of the DoH work in a virtual environment? “ and he pointed out, “Informed consent may be difficult to obtain, if not unpractical, and efforts to obtain it may not be justified in addition to a broad consent

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

and may stifle beneficial research, but there is no quick fix like “simple broad” or “one-time” consent. Secondary use is not the issue, multiple and often diversified use is intended from the beginning.

Use of databases in the course of individual treatment and the protection of public health should be dealt with separately. Risk and benefit can often not be defined in the beginning, thus they cannot be finally described and considered in a consent procedure at this point. Research use may not be the problem after all, but commercial, administrational and political use most likely will be, and differentiation and delineation may be a problem.

Dr Kloiber made some initial conclusions:

- Broad or one-time consent alone is not acceptable as it practically voids informed consent.
- Stringent use of informed consent is unrealistic.
- A specific solution only for research is neither practicable nor desirable.
- The challenge will be to ensure personal autonomy and dignity when donating or sharing specimen or data versus supporting ethical use of health database and biobanks (research and other uses).

Why there is a need of two Declarations:

Different Environments

Declaration of Helsinki (DoH)	Declaration of Taipei (DoT)
•Single research application	•Multiple uses
•Defined protocol with one hypothesis and one aim	•Multiple and different protocols •Multiple and different aims
•Risk can be described before recruitment	•Risk can usually not be defined before recruitment
•Defined timeline	•Timeline unknown
•The holder and user of data are known at the beginning	•The holder and user of the data may be different and users may not be known in the beginning
•Defined benefit	•Benefit undefined
•High Cost per data set	•Low cost per data set
•Data have to be collected	•The data set is available
•Subject data are usually identifiable	•User ID may remain anonymous or coded
•Intellectual property questions are usually subordinate to the subject/patient	•IP questions may be relevant for community and or individuals

Dr Kloiber concluded:

Proposed Solution in the Declaration of Taipei - on Ethical Considerations Regarding Health Databases and Biobanks (2016)

- Reaffirming the principles laid down in the Declaration of Helsinki
- Ethical review of the justification for the database or biobank
- Governance architecture

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

- Consent with Information about purpose, governance and procedures protection mechanisms to be applied in case of use
- Ethical review with any use of the database or biobank including a determination of additional measures (e.g. anonymisation or aggregation) or even individual consent as necessary

---

The webinar attracted 286 registered professionals, 111 finally connected.
Video-recording in YouTube is available:
https://youtu.be/vZFqSpDCBxo

For questions or comments to the content of the webinar you can send an email to:
secretary@wma.net with reference to the IFAPP webinar.

Authors:
Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs
Chieko Kurihara, BA, IFAPP Ethics Working Group, Specially-appointed Professor, Kanagawa Dental University, Editor-in-Chief, Clinical Evaluation

References:

1) World Medical Association. WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. First adopted October 2002, revised October 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

2) Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Collia LF, Kleist P, Laranjeira LF, Matsuyama K, Naseem S, Schenk J, Silva H and Kerpel-Fronius S. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future- Oriented Research Ethics. Front. Pharmacol. 2020. 11: 579714. http://doi: 10.3389/fphar.2020.579714

3) World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. First adopted in 1964, last amended in 2024. https://www.wma.net/policies-post/wma-declaration-of-helsinki/

4) Friesen, P., R. Douglas-Jones, M. Marks, R. Pierce, K. Fletcher, A. Mishra, J. Lorimer, C. Véliz, N. Hallowell, M. Graham, M. S. Chan, H. Davies, and T. Sallamuddin, "Governing AI-Driven Health Research: Are IRBs Up to the Task?," Ethics & Human Research 43, no. 2 (2021): 35-42. DOI: 10.1002/eahr.500085

5) ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Upcoming Congress on Pharmaceutical Legislation and Future Challenges: "Meet the Regulators"

15th Anniversary of Annual Meeting of BADI (Bulgarian Association of Drug Information), Sofia, Bulgaria, 9th October 2025

BADI is a non-governmental, non-profit organisation that unites over 60 corporate and 90 individual members. Its primary goal and mission are to work towards enhancing the qualification and professional competence of its members, as well as engaging in activities related to medicines regulations in public health.

BADI supports scientific research, education, and regulatory activities in the fields of pharmaceuticals, medical devices, food supplements, cosmetics, and other products related to public health. We have created a unique platform for a constructive dialogue between regulatory authorities, universities, industry professionals, and similar professional and non-governmental organisations.

Since its establishment in 2010, BADI has held over 120 training events (seminars, modular training courses, conferences, roundtables, discussions, and meetings), with more than 7,400 participants. These events have featured over 550 lecturers, including representatives from industry, academia, and regulatory authorities both in Bulgaria and abroad. Among our long-standing lecturers are over 120 internationally recognised professional drug regulatory experts from the UK, Germany, Denmark, Portugal, Switzerland, Poland, Finland, Norway, France, Austria, Hungary, Sweden, the USA, and more.

BADI is now pleased to announce its 15th anniversary at the upcoming congress that will take place in Sofia, Bulgaria, on 9th October 2025. The event will bring together key experts, policymakers, and industry leaders to discuss the latest developments in pharmaceutical legislation and the challenges ahead for the sector.
This year's congress will feature high-level speakers from European regulatory bodies and institutions, including the Executive Director of the European Medicines Agency (EMA) Emer Cooke and Mag Pharm. Bogdan Kirilov from the Bulgarian Drug Agency (BDA), who are expected to attend in person. Members of the Committee for Medicinal Products for Human Use (CHMP) are also part of the programme sharing their experiences.

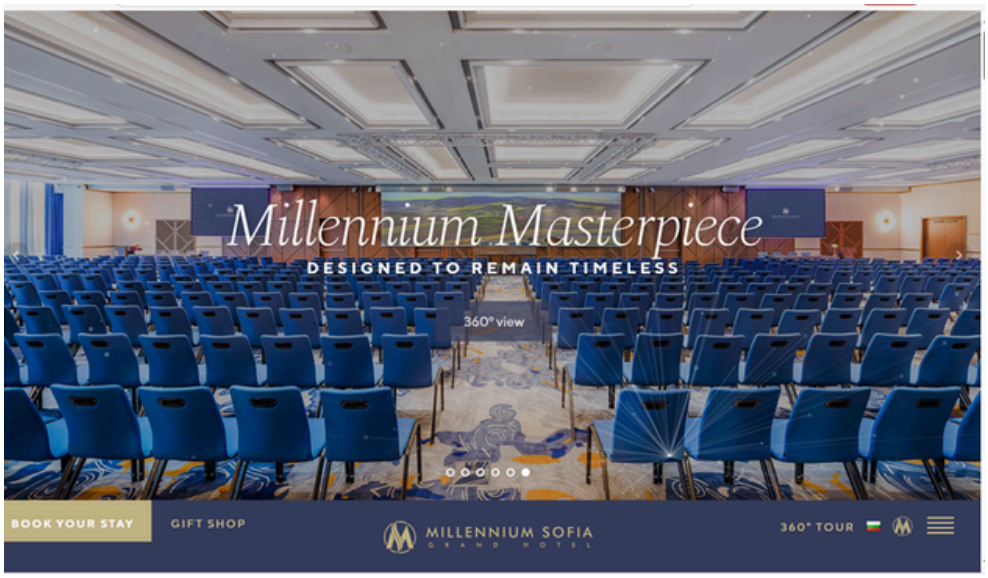
Discussions will focus on critical issues such as:
✅ New Provisions in the General Pharmaceutical Legislation – How will they shape the industry in the coming years?
✅ Regulatory Challenges and Market Access – Insights from leading CHMP members.
✅ Innovations and Future Policy Directions – Perspectives from the EU and international health authorities.

The congress will be in English language.

For more details, the **draft programme and registration** for the event, please visit this link.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The event will take place in the Grand Hotel Millenium in Sofia, providing a central and well-equipped venue for discussions and networking.



Revitalizing the Young Professionals Working Group - Volunteers Welcome

Since May 2025, I have had the privilege of serving as the interim chair of the Young Professionals Working Group (YPWG), stepping in until our group lead, Joanna Ramsey, returns to her role. During this interim period, I have been working closely with the group to re-energise our activities and broaden our outreach.

We are currently looking to welcome new participants both from within the IFAPP community and from the broader field of Pharmaceutical Medicine. Whether you are just beginning your professional journey or looking for ways to give back and engage, we would be very happy to hear fom you.

The YPWG is dedicated to raising awareness among early-career professionals about the field of Pharmaceutical Medicine, including available training opportunities and career pathways. One of our key aims is to promote the discipline by sharing relevant information at university career events and through student organisations, helping to inspire and guide the next generation of professionals.

Our work aligns closely with IFAPP's broader mission to advance Pharmaceutical Medicine in the context of the discovery, development, research, and responsible use of medicines.

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

In the coming months, we will be launching several new initiatives designed to support young professionals in both Pharmaceutical Medicine and clinical research. These efforts will offer a platform for international networking, professional development, and meaningful engagement with the wider IFAPP community.

To achieve our goals, we are seeking enthusiastic volunteers who are eager to contribute their time and expertise. Getting involved in the YPWG is a great opportunity to help shape the future of our field, while also building lasting professional connections across borders and disciplines.

Our next meeting will take place online on 10th July 2025, and I warmly encourage anyone interested to attend. Whether you are seeking to connect, contribute, or simply learn more, your involvement would be highly valued.

Let's work together to create a vibrant and inclusive space for the future leaders of pharmaceutical medicine!

If you are interested, please write an email to secretariat@ifapp.org .

Author:
Kateryna Uspenska, PhD, Gouya Insights GmbH & Co KG, Vienna, Austria

Digital Health Africa

// Digital Health Africa 2025

The Digital Health Africa 2025 Conference, taking place on 03-04 September 2025, will provide practical insights in the potential applications of digital technologies, using maternal and child health as important examples. Topics of interest will include patient registries, safety signals, vaccine use in pregnancy/breastfeeding, labelling of vaccines in pregnancy, emerging infections and antibiotic resistance, telemedicine, pharmacometric modelling, precision medicine, medicines regulation, ethical and legal aspects, and capability enhancement

Applying an integrated multi-site face-to-face and remote format, this hybrid Conference will use digital tools to allow delegates and speakers from three different regions, South Africa, Uganda and Germany, as well as fully virtual participants to engage with one another. This will offer a nexus for collaboration and networking to promote partnerships among local and international stakeholders as well as capacity building for young scientists. Delegates will have the opportunity to engage with

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

experts from industry, academia, healthcare providers, government and regulatory agencies as well as patient representatives to learn from one another and to gain valuable insights into the latest trends and best practices in digital health.

The abstract portal is now open: **Call for Abstracts – Digital Health Africa**

Accepted abstracts will be presented as interactive posters – a physical poster presentation at one of the conference sites; an e-poster and a 3-minute recorded presentation to accompany the poster. Presenters with accepted posters will be offered complementary conference registration.
digitalhealthafrica.org

Author:
Professor Catriona Waitt BSc (Hons), MBChB (Hons), MRCP, DTM&H, PhD
Professor of Clinical Pharmacology and Global Health

THE FLAG

IFAPP Secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Assem el Baghdady, Varvara Baroutsou, Francesco Butti, Brigitte Franke-Bray (Editor), Anna Jurczynska, Rita Lobatto, Hasan Mahmood, Kotone Matsuyama, Yasmin Nagaty (Editor), Helio Osmo, Joanne Ramsey, and Alexandra Reis Stoffel

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

Follow us on: