IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

Year-end Reflections from the President

Looking back on the activities and achievements of IFAPP in 2024 over the past few months, I would like to highlight the key achievements and challenges. In fact, the main achievements of the year can be listed as follows:

1. IFAPP's contribution to the 10th revision of the Declaration of Helsinki (DoH)

I am equally humbled and proud that we actively participated in the World

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Medical Association (WMA) 60th General Assembly in October this year and made a substantial contribution to the 10th revision of the DoH.

2. Since 2020 we have made a systematic effort by proposing the necessary changes to achieve the highest ethical standards through three major publications in peer-reviewed scientific journals and eight meetings organised by either IFAPP or the WMA. Ten out of twelve proposals by IFAPP's Ethics Working Group (EWG) have been included in the current version as mentioned in IFAPP TODAY, issue 39, on page 16. This great achievement is due to IFAPP's strategy and the hard work and persistent efforts of our EWG team (1-7).

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PERSPECTIVE

Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics

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TYPE Policy Brief

Declaration of Helsinki: ethical norm in pursuit of common global goals

OPEN ACCESS

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Vulnerability, social value and the equitable sharing of benefits from research: beyond the placebo and access debates

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3. IFAPP's strategy for public and patient engagement continues to evolve by listening to and working with patients as part of our efforts for the DoH revisions during the EWG webinars on 27 July and 26 August 2024.

4. Implementing the IFAPP 2024 Fellowships Awards was a successful project with 26 professionals being awarded the title of Fellow.

5. The renewed PharmaTrain Syllabus 2024 V3.0 was developed jointly by the Pharma Train Federation, the Faculty of Pharmaceutical Medicine, and IFAPP.

PharmaTrain Syllabus 2024 V3.0

Pharmaceutical Medicine/Medicines Development Science

Jointly developed by:
PharmaTrain Federation; Faculty of Pharmaceutical Medicine; International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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6. The new IFAPP website went live in September 2024 with a simple, friendly and modern feel and design.

7. The well-established IFAPP TODAY Journal is generating more members, loyal readers and followers based on the content and quality of the articles in Pharmaceutical Medicine.

8. The response of the IFAPP community to our monthly educational webinars is steadily increasing due to, e.g., the timely dialogue on key aspects across the spectrum of the European Union Clinical Trials Regulation (EU CTR 536/2014) implementation and its impact across continents, cross-border clinical trials, new technologies, advanced therapy medicinal products, ethics, pharmacovigilance, health technology assessment and medical devices.

9. IFAPP's increasing involvement with the WMA, CIOMS, PharmaTrain, Academia, regulatory bodies and its National Members Associations (NMAs) and Individual Affiliates (IAs) in Europe, the Middle East and Africa, Latin America, Asia and Australia is creating a global network of experts and Pharmaceutical Medicine professionals.

10. IFAPP's flagship event, the 21st International Conference of Pharmaceutical Medicine (ICPM 2025), co-organised with the Dutch Pharmaceutical Medicine Association NVFG in the Netherlands, is under intense preparation and will bring the public discourse on science, technology and medicines research and development into action in Amsterdam from 9 to 11 April 2025.

11. IFAPP's global presence with around 6000 members provides the opportunity to do more for patients and the public health.

In 2024, IFAPP faced several challenges, some of which are as follows:

- Keeping abreast of rapidly evolving science, regulations and international guidelines, with a mandate to continually update educational programmes to reflect the latest advances in Pharmaceutical Medicine, requires more resources to serve our members.
- In addition, the integration of new technologies and artificial intelligence (AI) into pharmacovigilance, clinical trials and research and development raises ethical and practical concerns that must be addressed by IFAPP's Working Group volunteers.
- There has been a reduction in income from unpaid membership fees as a result of the financial difficulties of IFAPP's NMAs and IAs.
- There is a lack of volunteers to support the IFAPP Working Groups' workload.
- Increasing operational costs strain already limited budgets and restricted funding.

Fortunately, our global collaborative network of stakeholders allows us to share knowledge, initiatives and resources to address ongoing challenges and encourages us to passionately succeed in our mission for the future of IFAPP.

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I, as IFAPP's President, would wholeheartedly like to invite all members, Fellows, readers and followers to join us actively in creating value for patients and better public health through the discipline of Pharmaceutical Medicine.

The year of 2024 has been a productive and inspiring year thanks to the IFAPP Executive Officers and Scientific Chairs, Working Group members and NMAs and IAs.

Working with our NMAs and IAs over the past year has been a great experience and we are proud to have you all with us.

I am deeply grateful for your contributions and wish you and your families a healthy, prosperous and creative 2025.

I welcome new members and look forward to further promoting Pharmaceutical Medicine with all of you, our partners and stakeholders.

Thank you for your commitment, cooperation and trust in IFAPP.

Dr Varvara Baroutsou
IFAPP President

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2025 IFAPP Fellowship Awards

Dear Colleagues,

It is with great enthusiasm that I write to invite you to participate in the 2025 IFAPP Fellowship Award programme. All award category descriptions, criteria, and submission information are listed below.

2025 IFAPP Fellowship Awards
Fostering Excellence and Professional Diversity

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 inpeer-reviewed journals.
   - A nomination letter from an IFAPP Board Member or NationalMember Association (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).
   - Short list 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, Biomedical, MPH,healthcare professional diploma).
   - Short list 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.

The deadline for submitting your application is Friday, 31 January 2025.
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.

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The date of the IFAPP Award Reception, where all awardees will be invited ,will be announced in September 2025.
Thank you in advance for your participation in this important process; your candidacy for these prestigious awards is greatly appreciated.

Varvara Baroutsou

Dr Varvara (Barbara) Baroutsou, IFAPP President

2025 IFAPP Fellowship Award Benefits

The IFAPP Fellowship Award 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 IFAPP in 2025 is now open until 31 January 2025. We encourage you to begin preparing your submission.

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 in 2025.
- Receive a certificate and a 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 2025.
- You will be informed of the decision with your application by the end of June 2025.
- If successful, you will be informed of the date of the award ceremony during September 2025.

The deadline for submitting your application is Friday, 31 January 2025.

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.

Collaboration with the WMA and Key Contribution to the 2024 Revision of the Declaration of Helsinki

1. Revision of the Declaration of Helsinki and IFAPP
The revised Declaration of Helsinki (DoH) (1) was adopted at the General Assembly (GA, 16-19 October 2024) of the World Medical Association (WMA).
Varvara Baroutsou, President of IFAPP, Kotone Matsuyama, Ethics Working Group (EWG) Chair, and Chieko Kurihara, EWG member, attended the GA and issued the "Helsinki Statement" (2), collaborating with external experts, and celebrating the 60th- anniversary of the DoH. Prior to this, Dr Baroutsou and Professor Kurihara had been invited as panellists to two different WMA's Meetings, one in Copenhagen, the other in Washington DC, respectively. In addition, IFAPP co-organised, in August 2024, together with other organisations, a two-day webinar of which the preprints have been published (3). During the whole process three peer-reviewed papers (4, 5, 6) to discuss specific topics of the revision of the DoH were released.

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2. WMA Regional Meetings in Copenhagen and Washington DC

When Dr Baroutsou was invited to the WMA's Copenhagen meeting in September 2023 to discuss "emerging clinical trial design", she introduced twelve recommendations from IFAPP (7) which had already formally been submitted to the WMA in 2019 as part of the Memorandum of Understanding (MoU) between the two organisations. Most of these were reflected in the 2024 Revision of the DoH, with two or three important issues remaining.

Professor Kurihara's participation in Washington DC in August 2024 was to discuss "Maximising Impact: Communication, Advocacy and Implementation". Other panellists of this session included the current President (at the time of the event) and the Secretary General of the WMA, the Past President of CIOMS who was the Working Group chair for the CIOMS Guidelines in 2016 (8), and a representative of a patient group. Professor Kurihara's presentation (Figure 1) was at the final stage of the whole revision process which had been initiated in April 2022.

During the panel discussion, Professor Kurihara introduced scientific papers and a published book elaborated with IFAPP about necessary changes of the DoH. Furthermore, she focused on the importance of engagement and co-creation with groups of patients and the public as well as experts (Figure 1). The publication of the "Helsinki Statement" was one of such initiatives.

Figure 1: A part of Professore Kurihara's presentation at the WMA meeting, August 2024.

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3. General Assembly in Helsinki

The WMA's GA was truly exciting and attractive. Not only the revision of the DoH but also various global issues were discussed, e.g. a scientific session entitled "Inequalities in Health and Health Care – How to Tackle them?" held on 17 October 2024.

Among the considerable number of documents adopted and/or discussed at the GA, the DoH was the highlight. The WMA press release (9) provides the summary and access to related papers in JAMA. A paper by the Working Group Chair of the DoH (10) cited a paper by members of IFAPP (8) in the context of promoting multidisciplinary collaboration for research, not just physicians' initiatives.

The final discussion on the revised DoH took place at the Medical Ethics Committee meeting on 16 October 2024. The draft reflected well the discussions during the process since April 2022, however, there were two "motions" from Uruguay to express disagreement with the paragraphs 33 on placebo use and 34 on post-trial access, reflecting Latin American countries' views (Table 1). The motions were rejected but raised remaining challenges.

4. Celebration for the 60th Anniversary

The 60th anniversary ceremony was held at the same place where the first DoH was adopted in 1964. One of the three video messages shown on the screen was by Professor Kurihara on behalf of IFAPP (photo). The other two messages were by Dr Ramin Parsa-Parsi, former working group chair of the 2013 revision of the DoH, who also chaired the revisions of the other two core documents cited in the DoH: the Declaration of Geneva and the International Code of Medical Ethics; and Dr Kati Millimaki, the former President of the WMA, from the Finnish Medical Association, well known as one of the "three wise women" who strongly contributed to the 2000 revision of the DoH which was the prior major amendment. The "three wise women" are a small group within the regular working group for the 2000 revision of the DoH, because there were so many controversial issues, e.g. conditions for placebo-controlled trials and ensuring post-trial access as well as the inclusion of publication of ethics issues such as conflict of interest disclosure, and positive/negative publication of results.

Table 1: DoH 2024 and motions from Uruguay on placebo and access

	DoH 2024	Motions from Uruguay Medical Association
Para 33	If proven intervention exists, placebo-controlled trials can be acceptable if:	
	· No "additional risks of **serious or irreversible** harm"	· No additional risks of harm (motion to delete "serious or irreversible")
	Similar position: ICH-E10 (11); DoH 2002～2013; CIOMS 2002	Similar position: DoH 1996; 2000; CIOMS 2016; IFAPP members' paper (5, 6)*; Helsinki Statement
Para 34	· Post-trial **provisions** must be **arranged**; · Exception must be approved by a research ethics committee	· Post-trial **access** provisions must be **guaranteed**; · Text for exception should be deleted
	Similar position: DoH 2004～2013	Similar position: DoH 2000; IFAPP members' paper (5, 6)*

* This does not mean that it is a consensus of IFAPP or IFAPP's Ethics Working Group.

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Photo: *Video message given by Professor Chieko Kurihara at the Ceremony at the restaurant Töölön Juhlasali where the DoH was firstly adopted in 1964, offered by the Finnish Medical Association*

5. Helsinki Statement

The "Helsinki Statement (2)" is an initiative, independent of the WMA and IFAPP, organised by stakeholders who globally share the common goals of seeking the highest ethical standards for research ethics (signed by 109 individuals and 3 groups from a total of 19 countries, many of which are from the Global South and Asia, as of 7 November 2024. Japanese and Arabic translations are available (3)). The statement consists of two parts (Table 2). It was discussed at two web-meetings (15 and 20 October 2024) broadcasted from Helsinki to a worldwide audience, In parallel, it was reported to the WMA on the date of the first official announcement (18 October 2024). The first part is praising most of the changes and the second part refers to a few remaining controversial issues, although not all IFAPP members have the same perspective. Continuing discussions on these points would contribute to better protection of research participants as well as the integrity of responsible research involving humans.

The full report including interviews with key persons is planned to be published by Clinical Evaluation (3).

Table 2: Composition of the Helsinki Statement (summary, texts may not be the same as those of the DoH and the Statement.)*

Celebrate the DoH 2024 for the revisions: 1. Change research subjects to research participants; 2. Scope to include non-physicians, teams, organisations; 3. Recognition of various structural inequity in research; 4. Meaningful engagement with participants and their communities at all the stages of research; 5. DoH must be adhered to in public health crises; 6. Inclusion of vulnerable people with adequate protection, recognizing contextual vulnerability; 7. Strengthened research ethics committee reflecting community values; 8. The preferences and values of incapable research participants shall be considered; 9. Data and specimens from research shall be handled in accordance with the Declaration of Taipei on health databases and biobanks; 10. Clinical use of unproven intervention must never be undertaken to circumvent the protection set forth in the DoH.
Remaining challenges: 1. Plain language understandable for patients and the public; 2. Promoting consideration on "social value"; 3. Risk minimisation in placebo-controlled trials; 3. Post-trial access for participants who still need it, as well as for those in need in host community and globally.

* This is not an official statement of IFAPP, as some IFAPP members have participated individually

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Chieko Kurihara, Ethics Working Group, IFAPP
Kotone Matsuyama, Chair of Ethics Working Group, IFAPP
Varvara Baroutsou, IFAPP President

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References:

1) WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. 2024.
2) Helsinki Statement Stakeholders. Helsinki Statement 2024. Clin Eval. 2024; 52(3).
3) Clin Eval. 2024; 52(3).
4) 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.
5) Kurihara C, Kerpel-Fronius S, Becker S, Chan A, Nagaty Y, Naseem S, Schenk J, Matsuyama K, Baroutsou V. Declaration of Helsinki: ethical norm in pursuit of common global goals. Front Med. 2024 Apr 2;11:1360653. PMID: 38628806; PMCID: PMC11019506
6) Kurihara C, Greco D, Dhai A, Matsuyama K, Baroutsou V. Vulnerability, social value and the equitable sharing of benefits from research: beyond the placebo and access debates. Front. Med. 2024; 11:1432267.7
7) Baroutsou V. Exploring New and Emerging Trial Designs Considering the Revision of the Declaration of Helsinki. IFAPP TODAY. 2023; Nov/Dec (39): 14-17.
8) Council for International Organizations of Medical Sciences. International ethical guidelines for health-related research involving humans. 2016.
9) World Medical Association. 21October 2024.
10) Resneck JS Jr. Revisions to the Declaration of Helsinki on Its 60th Anniversary. JAMA. 2024 Oct 19.
11) ICH harmonised tripartite guideline: choice of control group and related issues in clinical trials E10.2000.

The revised Declaration of Helsinki

Is it fit for purpose?

The 2024 revision of the Declaration of Helsinki (DoH) (1) published on 19 October 2024 revisits many of the issues of controversy in its previous versions: There were nine versions between 1964 and 2013, the 2024 version being the 10th in its 60 years of history as a major international document in research ethics. The changes to this new version are sometimes obvious and in long need of updating (e.g., from 'research subjects' to 'research participants'). However, overall, this new and substantial revision fails in two important ways:

1. The revision does not clarify substantially important issues, including consent, vulnerability, the role of research ethics committees, the use of placebo in clinical trials, and access to medicines post-trial. Not only does it not clarify these issues, but the several lengthy additions of requirements are also incomplete and more often than not introduce further confusion that cannot be reconciled within the DoH.
2. The revision fails to address some of the most current and relevant issues in the ethics of medical research: The ethical questions posed by health emergencies, the impact of electronic means for informed consent, the impact of genomics in research, the use of artificial intelligence (AI)-driven systems in medical research, the full extent of medical research outside of clinical trials.

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Further, the 2024 DoH version lacks exactitude in wording, makes assumptions that are vague and cannot be substantiated, and presents requirements that are beyond the scope of what is actual or even possible in contemporary medical research practice. Beyond this, the DoH is undermined by the increased push by the World Medical Association (WMA) to go beyond its own remit as an international corporation of physicians and assert a 'mandate' to impose its rulemaking for physicians on all those involved in medical research, including those from other disciplines (all researchers), research teams, institutions, authors, editors, and publishers.

This calls into question the role of a private organisation where member organisation voting rights vary according to the amount of money each member organisation pays while sponsorship from the pharmaceutical industry supports a two-and-a-half-year revision process. Further, the DoH states that physicians and researchers 'consider' national and international ethics, regulatory, and legal norms and requirements, but asserts that its rulemaking is above these norms and requirements and 'should' or 'must' be followed. The failure of the WMA to understand its role and place in the international discourse on ethics and medical research undermines the DoH.

The launch of the 2024 revision of the DoH has been greeted with near exclusive praise and celebration, and little substantial criticism (2). Perhaps this new version of the DoH is deserving of this near universal and immediate acceptance. Perhaps not. Ethics, however, is a place for conversation and debate.

Nevertheless, the WMA and its revised DoH are not solely or entirely at fault. The global community of physicians 'and other researchers' as well as ethicists, ethics committees, and regulatory authorities are perhaps failing patients, medicine, and the global medical research ecosystem in their acceptance of a flawed, incomplete, and confused document as a benchmark for the ethics of medical research. The reform of medical ethics such that it is fit for purpose in today's world requires a fundamental reform of our conversation of what is acceptable and what is not acceptable in research on human participants. A closer look at the revised DoH (3) raises questions as to whether it is a guideline that should be implemented for the protection of the rights of research participants.

Author: **Francis P. Crawley**, Member, IFAPP Ethics Working Group

References:

1) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human participants. JAMA. Published October 19, 2024.
2) Bibbins-Domingo K, Brubaker L, Curfman G. The 2024 Revision to the Declaration of Helsinki: Modern Ethics for Medical Research. JAMA. Published online October 19, 2024 and the full set of articles in this JAMA issue where 'The commentors applaud the Declaration of Helsinki as a living document built on a solid ethical foundation; they see the 2024 revision as responsive to contemporary issues in medical ethics.'
3) Crawley, F. P. (2024). Declaration of Helsinki: Full paragraph-by-paragraph comparison indicating changes in version 19 October 2024 compared with the most previous version of 19 October 2013. Zenodo.

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Expectations of Young Professionals in Pharmaceutical Medicine

Young professionals in Pharmaceutical Medicine, i.e. working in the field of drug development both in academia and industry, are driven by the desire to improve treatment options for today's diseases and/or medical conditions, thus making a meaningful impact on public health. New technological advancements, namely the CRISPR/Cas gene editing method [1], the use of mRNA to develop vaccines [2] or AlphaFold2 helping researchers in predicting protein structures [3], just to name a few, have deeply changed the drug development landscape. In this dynamic field, young professionals need to find their place: they want to build up their careers and contribute to new therapeutic advancements while at the same time having to deal with social and environmental challenges.

In our opinion, young professionals in Pharmaceutical Medicine want to fulfil three main expectations related to their work environment:

1. Interdisciplinary Collaboration and Learning

According to surveys conducted by the International Pharmaceutical Federation (FIP), young professionals seek career opportunities that offer continuous learning, mentorship, and leadership development. They also value structured training programmes that align with global competencies in drug development and pharmaceutical sciences. [4,5]

In Switzerland, for example, medical doctors can specialise in the field of Pharmaceutical Medicine. During their training, they acquire a deepened knowledge about the drug development process, from pre-clinical studies to clinical trials up to marketing authorisation of the products. [6] However, currently, there are not enough positions as assistant doctors for this specialisation considering the vast interest and we need to fund more positions in both academia and industry in the future. The newly trained specialists in Pharmaceutical Medicine are able to provide the highest professional standards for the benefit of the patients and the public. As medical doctors from both academia and industry can undergo this training, regular interdisciplinary exchange between the respective fields is promoted and professional networks are strengthened.

An international example for interdisciplinary collaboration is the Young Professionals Working Group (YPWG) from the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). This working group provides general knowledge on how the pharmaceutical industry works for interested members, fosters cross-functional international teamwork by offering continuous learning and training programme opportunities in drug development to medical doctors and scientists and informs them about new career opportunities. [7]

2. Social Responsibility

Climate change is one of the biggest crises of our time having an impact on both individual and global health, already now and in the future. [8] Young professionals increasingly expect pharmaceutical companies and hospitals to act socially responsible, focusing on areas such as climate responsibility, sustainability, and ethical behaviour. Scientists and medical doctors expect their employers to demonstrate what they advocate, matching their actions with declared values.

Health professionals want to promote climate actions required from individuals, organisations and governments. [9] Consequently, corporate social responsibility has turned into a key element for recruiting and keeping skilled individuals. For young professionals, corporate social responsibility and ethical considerations are an essential part of work life.

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3. Working Conditions

As shown by Sanchez-Hernandez et al, younger generations increasingly prioritise flexibility and a healthy balance between their work and personal lives. [10] They tend to seek workplaces that offer a good work-life-balance, including remote work and flexible hours, and part-time job opportunities to combine most effectively work responsibilities, family duties and hobbies. Companies are encouraged to address these expectations to attract and retain young talent, and to consider that happy employees are 13% more productive, according to Bellet et al [11]. Young professionals look for inclusive work environments where different perspectives are welcomed and innovation stems from a wide range of voices. They want to be included in decision-making according to their level of expertise. The top-down approach to management needs to coexist to bottom-up decisions [12].

In summary, the expectations of young professionals working in drug development are multifaceted, combining the desire for scientific innovation with modern values of work-life balance, diversity and social responsibility. Young professionals are ambitious and driven by a sense of purpose, aiming to contribute to advances in healthcare while maintaining high ethical standards and a positive work environment. Organisations that can meet these expectations by fostering innovation, providing career growth, ensuring ethical practices and promoting a healthy work-life balance, will not only attract highly motivated medical doctors and scientists but also set the stage for continued success in a rapidly evolving healthcare system.

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Illustration:
The three main expectations of young professionals in Pharmaceutical Medicine

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References:

1. JINEK, M., CHYLINSKI, K., FONFARA, I., HAUER, M., DOUDNA, J. A. & CHARPENTIER, E. 2012. A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity. Science, 337, 816-21.
2. The Nobel Prize. 2023. The Nobel Prize in Physiology or Medicine 2023 [Online]. Available: https://www.nobelprize.org/prizes/medicine/2023/press-release/ [Accessed 04th November 2024].
3. The Nobel Prize. 2024. The Nobel Prize in Chemistry 2024 [Online]. Available: https://www.nobelprize.org/prizes/chemistry/2024/press-release/ [Accessed 04th November 2024].
4. MANIKKATH, J., MATULUKO, A., LEONG, A., CHING, D., DEWART, C., LIM, R., MEILIANTI, S. & UZMAN, N. 2020. Exploring young pharmacists' and pharmaceutical scientists' needs and expectations within an international pharmacy organization: Findings from FIP's needs assessment survey. Res Social Adm Pharm, 16, 1677-1685.
5. MEILIANTI, S., MATULUKO, A., IBRAHIM, N., UZMAN, N. & BATES, I. 2022. A global study on job and career satisfaction of early-career pharmacists and pharmaceutical scientists. Explor Res Clin Soc Pharm, 5, 100110.
6. SCHNETZLER, G., BREMGARTNER, M. F., GROSSMANN STRAESSLE, R., SPIRK, D., TAY, F., TROXLER SAXER, R. & TRABER, M. 2019. Evolution to a Competency-Based Training Curriculum for Pharmaceutical Medicine Physicians in Switzerland. Front Pharmacol, 10, 164.
7. IFAPP. 2024. Young Professionals Working Group [Online]. Available: https://ifapp.org/working-group/young-professionals/ [Accessed 04th November 2024].
8. ROMANELLO, M., DI NAPOLI, C., DRUMMOND, P., GREEN, C., KENNARD, H., LAMPARD, P., SCAMMAN, D., ARNELL, N., AYEB-KARLSSON, S., FORD, L. B., BELESOVA, K., BOWEN, K., CAI, W., CALLAGHAN, M., CAMPBELL-LENDRUM, D., CHAMBERS, J., VAN DAALEN, K. R., DALIN, C., DASANDI, N., DASGUPTA, S., DAVIES, M., DOMINGUEZ-SALAS, P., DUBROW, R., EBI, K. L., ECKELMAN, M., EKINS, P., ESCOBAR, L. E., GEORGESON, L., GRAHAM, H., GUNTHER, S. H., HAMILTON, I., HANG, Y., HANNINEN, R., HARTINGER, S., HE, K., HESS, J. J., HSU, S. C., JANKIN, S., JAMART, L., JAY, O., KELMAN, I., KIESEWETTER, G., KINNEY, P., KJELLSTROM, T., KNIVETON, D., LEE, J. K. W., LEMKE, B., LIU, Y., LIU, Z., LOTT, M., BATISTA, M. L., LOWE, R., MACGUIRE, F., SEWE, M. O., MARTINEZ-URTAZA, J., MASLIN, M., MCALLISTER, L., MCGUSHIN, A., MCMICHAEL, C., MI, Z., MILNER, J., MINOR, K., MINX, J. C., MOHAJERI, N., MORADI-LAKEH, M., MORRISSEY, K., MUNZERT, S., MURRAY, K. A., NEVILLE, T., NILSSON, M., OBRADOVICH, N., O'HARE, M. B., ORESZCZYN, T., OTTO, M., OWFI, F., PEARMAN, O., RABBANIHA, M., ROBINSON, E. J. Z., ROCKLOV, J., SALAS, R. N., SEMENZA, J. C., SHERMAN, J. D., SHI, L., SHUMAKE-GUILLEMOT, J., SILBERT, G., SOFIEV, M., SPRINGMANN, M., STOWELL, J., TABATABAEI, M., TAYLOR, J., TRINANES, J., WAGNER, F., WILKINSON, P., WINNING, M., YGLESIAS-GONZALEZ, M., ZHANG, S., GONG, P., MONTGOMERY, H. & COSTELLO, A. 2022. The 2022 report of the Lancet Countdown on health and climate change: health at the mercy of fossil fuels. Lancet, 400, 1619-1654.
9. DOBSON, J., COOK, S., FRUMKIN, H., HAINES, A. & ABBASI, K. 2021. Accelerating climate action: the role of health professionals. BMJ, 375, n2425.
10. SANCHEZ-HERNANDEZ, M. I., GONZALEZ-LOPEZ, O. R., BUENADICHA-MATEOS, M. & TATO-JIMENEZ, J. L. 2019. Work-Life Balance in Great Companies and Pending Issues for Engaging New Generations at Work. Int J Environ Res Public Health, 16.
11. BELLET, C. S., DE NEVE, J. E. & WARD, G. 2024. Does Employee Happiness Have an Impact on Productivity? Management Science, 70, 1656-1679.
12. BJÖRK, J. M., BOLANDER, P. & FORSMAN, A. K. 2021. Bottom-Up Interventions Effective in Promoting Work Engagement: A Systematic Review and Meta-Analysis. Frontiers in Psychology, 12.

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Learning Pharmaceutical Medicine in the Age of Public Engagement in Japan

Pharmaceutical Medicine is a medical specialty applied to professional drug development scientists worldwide. Recently, in Japan, education of patients and the public is also encouraged in promotion of their participation in Ethics Review Committees, but filling the gap of knowledge, information, and disease experience between clinical trial professionals and patients and the public is not easy. Here we introduce the efforts of the Japanese Institute for Public Engagement (hereinafter referred to as Ji4pe), providing various learning courses to all stakeholders to facilitate public participation, with points to consider the current issues and prospects.

Educational Courses in Pharmaceutical Medicine

Pharmaceutical Medicine has been defined since the 1970s by the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) by standardising the educational syllabus and course structures to develop drug development specialists, followed by the PharmaTrain Federation (hereinafter referred to as "PharmaTrain") (1) established in the EU accrediting the courses worldwide.

In Japan, following the course sponsored by Osaka University (2) and the Japanese Association of Pharmaceutical Medicine (3), there are courses sponsored by Ji4pe (4) since June 2020. Both institutions are accredited by PharmaTrain as Centres of Excellence (CoE) (5).

Ji4pe's Educational Courses

Ji4pe offers two courses for corporate employees and medical institution staff; the PharmaTrain certified C-course (From Drug Discovery to Post-marketing and Health Economics), and the D-course (Specialist in Medicines Development Programme) for those who have completed the C-course and whose competencies in drug development have been objectively proved. For patients and public participants, the A-Course can guide introduction to drug development and medical communication. The B-Course can support the development of organisational structures and human resources for patient associations, and the E-Course offers education and training necessary for those who are willing to contribute as members of Ethical Review Committees. Figure 1 shows the educational courses, training and consulting service offered by Ji4pe. Basically, courses are open to everyone who wants to learn (except for the D-course), and those who have completed the course and met the PharmaTrain criteria as instructors can contribute to the following courses by facilitating practical discussions among all stakeholders.

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PharmaTrain

Figure 1 : Ji4pe's educational courses, training and consulting service

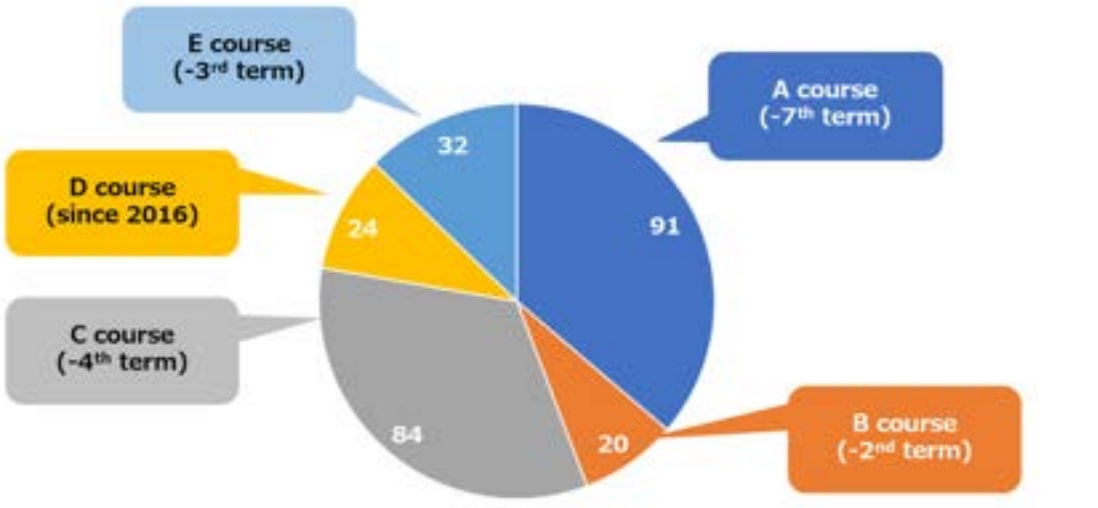
Category	Courses	Schedule
Public Engagement Expert Training Course	A. Introduction to drug development and use in the market	Saturday afternoon, 4Wks
	B. Leadership training for representatives of patient associations and advocacy groups	Saturday afternoon, 8Wks
	C. Basic knowledge in drug development, aligned with PharmaTrain Syllabus v2.0	1-year
	D. PharmaTrain's SMD (Specialist in Medicines Development) program for drug developers	1-year or more
	E. Educational course for non-scientific members of ECs/IRBs	Saturday afternoon, 4Wks
Workplace training for clinical trial professionals	Lectures and workshops at workplace for better understanding and challenge for reform	On demand
Joyful learning for Kids	Case studies and references provided in Manga	—
Consulting service to address questions in public engagement	Coordinating patient interviews upon request of companies and associations	On demand

https://ji4pe.tokyo/introduction.html

Figure 2 shows the number of participants who have taken courses A to E, since the establishment of the corporation in June 2020 and until October 2024.

PharmaTrain

Figure 2 : Participation to Ji4pe courses



Between June 2020 and October 2024 (limited to open courses)

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Current Issues in Drug Development

It has been expected that promoting "patient-centred processes" and "patient participation" may contribute to the operation of clinical trials by utilising the experience of patients and trial participants. In the past, patients were rarely involved in the development of clinical study protocols or consent forms, but recent emphasis on international patient participation and the spread of telecommuting and online medical consultations made available during the COVID-19 pandemic also promoted communication in and out of patient associations. In addition, the widespread use of devices such as smartphones and smartwatches suggests that the development of medical technology for individual reporting is expected. As a result, we see a remarkable increase in the number of patient interviews and surveys asking their views online and what attracted their preferences in remote trials, although the gap of knowledge in drug development often invites misunderstandings in their exchanges.

Patient Association Activities and Public Interest

As is seen in the patient group survey report (6) conducted by the Patient Group Collaboration Promotion Committee of the Japan Pharmaceutical Manufacturers Association, patient association activities in Japan are generally small in scale, have little budget, and the founding members of the association are worn out with no successor. Some patient associations have revitalised by adopting the online services mentioned above, while others say it is difficult. The success of crowdfunding is not always the case partly because patient association activities are not considered to bring public benefit.

Since its establishment, Ji4pe has offered the B-course in hope of developing patient association activity as an organisational and not an individual advocacy. There are various remedial measures in Japan, such as a universal health insurance coverage, a high-cost medical care expense scheme, and a rescue programme for designated intractable diseases, but to maintain their sustainability it is important to emphasise that patient association activities should be taken as public (not individual) interest, and that the participation of public is critical to gain more diversity in communication.

In fact, in Ji4pe courses and workshops by the member working groups, all stakeholders can get together and listen to the voice of the patients. For corporate employees and medical institution staff, who tend to be biased towards the developer's point of view, learning together can bring an eye-opening experience.

Future Prospects

To invite more participation to public engagement, their unmet needs must be clarified. Ji4pe is planning to conduct research in 2025 to initiate online surveys with the help of its member organisations. Based on the survey results, we should be able to adapt the contents of education and training so that patient associations can effectively acquire the knowledge and the skills necessary to solve their problems, which may result in more satisfaction and contribution to the society.

Author: Kyoko Imamura, MD, PhD
President, Japanese Institute for Public Engagement (Ji4pe)

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Literature/References:

(1) PharmaTrain Federation.
(2) Clinical Research Professional (CRP) Course, Osaka University.
(3) Japanese Association of Pharmaceutical Medicine.
(4) Japanese Institute for Public Engagement.
(5) PharmaTrain Course Providers.
(6) Japan Pharmaceutical Manufacturers Association Patient Group Collaboration Promotion Committee, Patient Group Survey Report.
(7) Japan Pharmaceutical Manufacturers Association Patient Group Collaboration Promotion Committee, Patient Group Survey Report.

Free Webinars in early 2025

23 January 2025 | 12:00 noon – 1:00 pm CET
The European Young Persons Advisory Group Network (eYPAGnet)
Speaker: **Begoña Nafría Escalera** (Sant Joan de Déu/Barcelona, Spain)

20 February 2025 | 1.00 to 2.00 pm CET
Declaration of Helsinki Update
· What is new for Ethics Committees?
· What is new for conducting clinical trials and everyday treatment?
Speaker: **Prof. Dominique Sprumont** (University Neuchâtel, Switzerland)

20th March 2025 | 11:00 am to 1:00 pm CET
Cardiovascular Gender Pharmacology
Speaker: **Dr Rubén Fuentes Artiles** (University Clinic/Inselspital Berne, Switzerland)

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The External Affairs Working Group (EAWG) of IFAPP in 2024: Report 2024

The EAWG is responsible for establishing and maintaining strategic partnerships with key stakeholders, including IFAPP National Member Associations, professional associations, government agencies, and other organisations. In 2024, the EAWG undertook several strategic initiatives and collaborations to advance Pharmaceutical Medicine.

The working group ensured that IFAPP's registration on the EU Transparency Register was validated. With registration number REG 970411692295-33, this step was essential for communication with EU institutions and participation in public consultations.

The team submitted also an application form to request EMA eligibility status for healthcare professionals' organisations in order to be involved in EMA activities. The application is under evaluation, and IFAPP will be informed of the outcome upon completion.

The EAWG initiated also discussions for a partnership with the FDA, focusing on regulatory and safety aspects, possibly leading to a Memorandum of Understanding (MoU) between both organisations.

Engaging with patient organisations has always been a priority, ensuring patient perspectives were considered in the development and use of medicines. This alignment with patient needs reinforced IFAPP's patient-focused approach. Further formalisation with specific organisations still needs to be done.

The EAWG has successfully established and maintained strategic alliances over the years with various stakeholders to raise awareness of IFAPP's vision and mission. These partnerships have been crucial in promoting Pharmaceutical Medicine at both international and national conferences, symposia, and other forums.

IFAPP strengthened ties with National Member Associations, promoting IFAPP's mission at various international and national conferences, symposia, and fora.

These activities and initiatives undertaken by the EAWG in 2024 helps to raise IFAPP's profile globally and reinforce IFAPP's position as a leading organisation in Pharmaceutical Medicine.

Author: **Robert Lins**, MD, PhD, IFAPP External Affairs Working Group Chair

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Patients' Cross-Border Access to Clinical Trials – The Unmet Global Need for Patients and Clinical Researchers - IFAPP Webinar of 17 September 2024

Moderator: Birka Lehmann, IFAPP ECWG

Speakers:
Teodora Lalová-Spinks, KU Leuven, Belgium
Emilie Prazaková, Roche, Switzerland
Dariusz Zebrowski, StopDuchenne Foundation

Panellist: Ingrid Klingmann
Patients with life-threatening or rare diseases and patients living in research-poor countries are interested in joining a clinical trial in another country because that might be the only treatment option. And investigators could reduce their recruitment struggles if they were able to enrol patients from other countries. But, in reality, such participation is very difficult to implement and therefore hardly happens.
This webinar focused on the needs, the financial, ethical, regulatory and organisational hurdles and best practice examples, and informed about a European initiative aiming at facilitating such participation in practical terms.

Teodora Lalová- Spinks presented the results of such a study and underlined the needs for cross-border clinical trials and the challenges to facilitate this kind of clinical trials.

Emilie Prazaková informed about the actions taken making cross-border access to clinical trials a reality by setting up the EU-X-CT Initiative.

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EU-X-CT Initiative Mission

Based on the EU's principle of freedom of movement, participation in a clinical trial abroad is **theoretically possible**. However, there is no specific European legislation or guidance on facilitating cross-border clinical trial participation

Participation in a clinical trial is an important element of healthcare, especially for **patients with life-threatening and/or rare diseases** for whom a medicinal product under investigation might be the only therapeutic option.

The EU-X-CT Initiative is reaching out **to enable cross-border access to trials for patients** when there is no option for them to join a clinical trial in their own country

M-XX-0008821 September 2024

The initiative already worked on several aspects like ethical, legal, regulatory and financial aspects of cross-border trials

The EU-X-CT gap analysis

EUXCT

Summary of the interim analysis of the surveys

- **Cross-border trials are not explicitly forbidden in any country.** However, the lack of clarity and specific legal and regulatory guidance leads to a very cautious approach to cross-border participation for major stakeholders (sponsors, investigators, patients).
- **Cross-border access is currently managed on a case-by-case basis** and is associated with a high logistical and administrative burden (if not entirely covered by industry trial sponsors).
- **'Who pays for what' is the most critical issue.** Access to insurance coverage is needed, also for background treatment and trial-related injuries. Travel and accommodation costs can mean potentially high upfront out-of-pocket expenses for patients.
- **Language barriers might impact a patient's ability to understand risks.** Patients must be able to make an informed decision about joining the trial. There are also concerns about cultural differences in healthcare practices, the burden of frequent relocation for patients, and the potential impact on a patient's decision regarding risk.
- **Decentralized trial elements** across border may not be feasible in certain countries, although they might be the best option for patients.

M-XX-0008821 September 2024

The EU-X-CT initiative defines the most urgent goals to make this approach sustainable.

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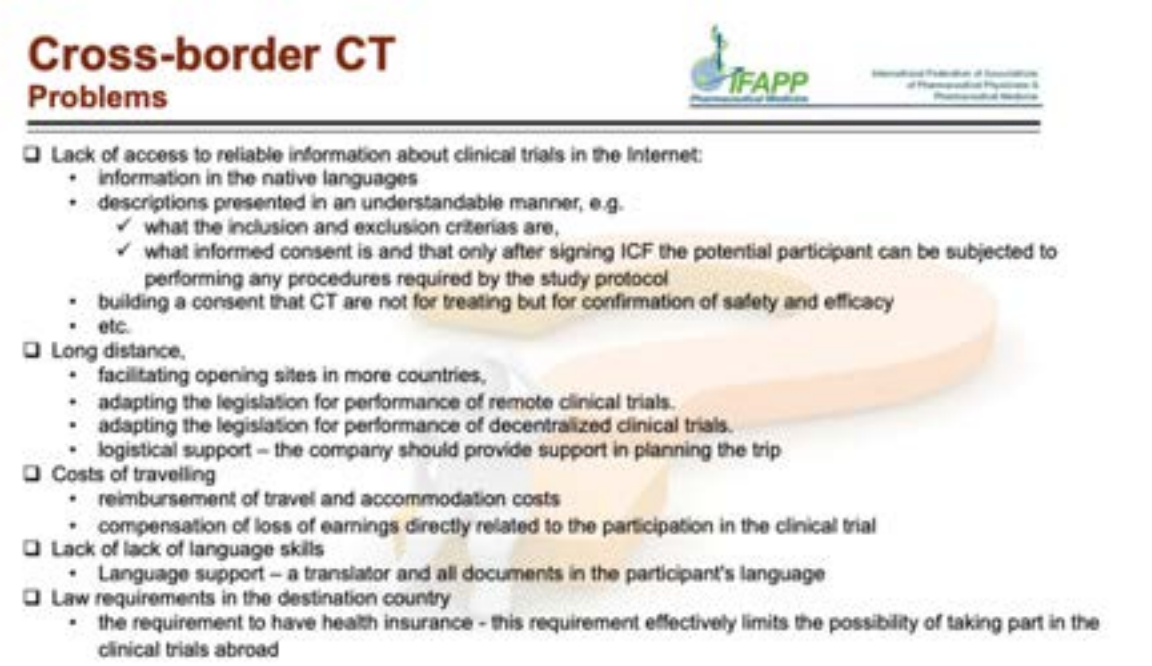
Dariusz Zebrowski presented the view of the patients based on his own experience with participation in a cross-border trial.



The EU-X-CT initiative defines the most urgent goals to make this approach sustainable.

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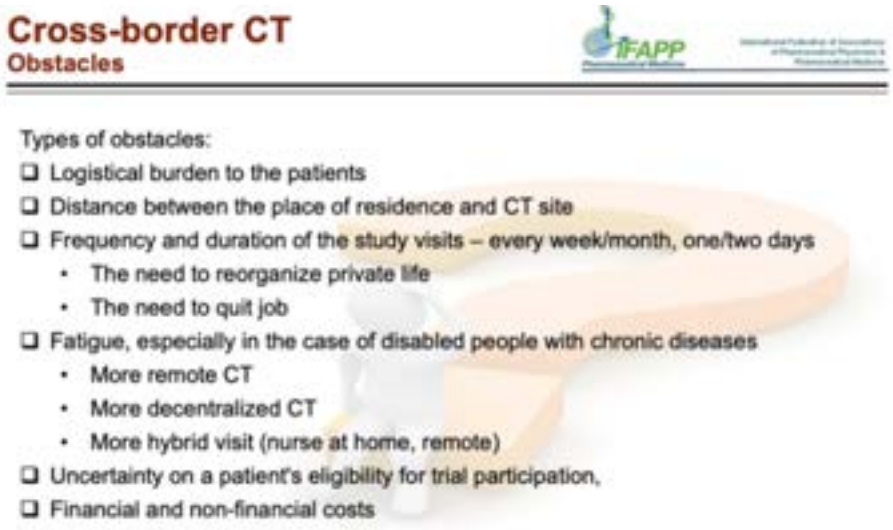

In summary, all speakers agreed that the main issue was in relation to information about clinical trials at all and that it would be necessary to create an infrastructure to serve the needs of the patients.

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

The Evolving Regulatory/HTA Interface under the New European Health Technology Assessment (HTA) Regulation - IFAPP Webinar of 17 October 2024

Moderator: Birka Lehmann, IFAPP Education and Certification Working Group (ECWG)

Speakers: Anne Willemsen, Zorginstituut Nederland,
Co-Chair Joint Clinical Assessment (JCA) Subgroup
Michael Berntgen, European Medicines Agency (EMA) Head of Scientific Evidence Generation Department

Close interaction between regulators, HTA bodies and EMA is critical to enable patient access to important new medicines and hence for the benefit of public health. This aims to reduce developmental resources by re-shaping and focusing medicine development programmes to generate evidence relevant for regulators, HTA bodies and other stakeholders.
Cooperation also aims to facilitate sequential decision-making by sharing information in the context of the respective assessments.

Anne Willemsen gave a short introduction regarding the responsibilities of the different organisations within the framework of the new Health Technology Assessment Regulation (HTAR).

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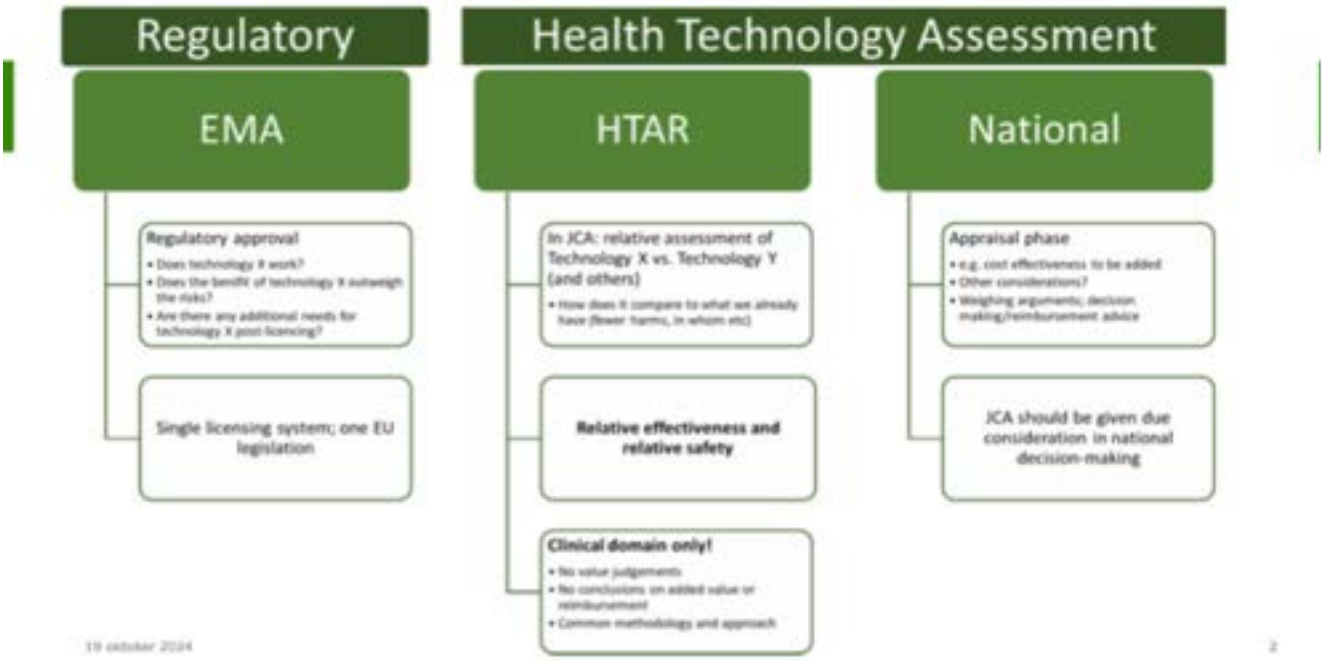

This was followed by the presentation of the scope of the HTA Regulation and the rolling plan for implementation.

Scope of the HTA Regulation

- Medicinal Products
  - From Jan. 2025: oncology and ATMPs
  - From Jan. 2028: orphan drugs
  - From Jan. 2030: full scope
  - Includes Type II variations, once a JCA has been conducted on the initial indication
  - See Scientific specifications of MP subject to JCA for details
- Medical Devices
  - High risk MD, Type IIb, III and IVD

Joint Scientific Consultation (JSC)	Joint Clinical Assessment (JCA)
DEFINITION	
- Scientific advice - provided jointly by HTA bodies - Can be in parallel with regulators - To HTD on the clinical development	- Joint HTA reports, produced by 2 EU MS - On HTD submission dossier - HTD can't submit data again on national level - **Clinical domains; no value judgements** - MS to give due consideration
AIM	
To generate evidence that satisfies the needs of HTA bodies during their assessment and ultimately facilitates patient access	To avoid duplications of work at the national level, increase consistency and quality of assessments and ultimately facilitate patient access
RELEVANT ARTICLES IN THE HTA REGULATION	
Art. 16 – Art. 21 Covering principles of JSC; Requests for JSC (& selection criteria); Preparation of JSC; Approval of JSC; Format and template for JSC	**Art. 6 – Art. 15** Covering annual work plan; Health technologies subject to a JCA; Initiation & PICO development; Obligations of HTD; Assessment process; Obligations Member States; Update of JCA

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Rolling Plan & extract of anticipated documents

Rolling plan - Implementation of the Regulation on health technology assessment - European Commission (europa.eu)

1st	Procedural rules for JCA of medicinal products	Adopted 23 May
2nd	Procedural rules for the management of conflicts of interest	Positive opinion of the HTA Committee on 27 September
3rd	Procedural rules on the cooperation with the EMA	Adopted on 18 October
4th	Procedural rules for JSC of medicinal products	Published for public feedback DDL: 29 October
5th	*Procedural rules for JSC of medical devices and IVD medical devices*	*In preparation*
6th	*Procedural rules for JCA of medical devices and IVD medical devices*	*In preparation*

Anne pointed out the difference between EU and national assessments.

EU vs National assessment (The Netherlands as example)

EU assessment

- Starting point: HTD centrally submits clinical dossier and analysis
- 2 MS write JCA report
  - *No conclusion on added value or reimbursement*
- Clinical assessment report published on IT platform
- Submission dossier published too

National assessment

- Starting point: receive Dutch submission dossier (incl. JCA report)
  - ZIN to give due consideration to JCA & not allowed to ask for data that is already submitted on EU level
- ZIN write national report (+ budget impact analysis and cost-effectiveness if needed)
  - GRADE & Evidence to Decision
  - Dutch appraisal committees involved
- ZIN publishes advice on website

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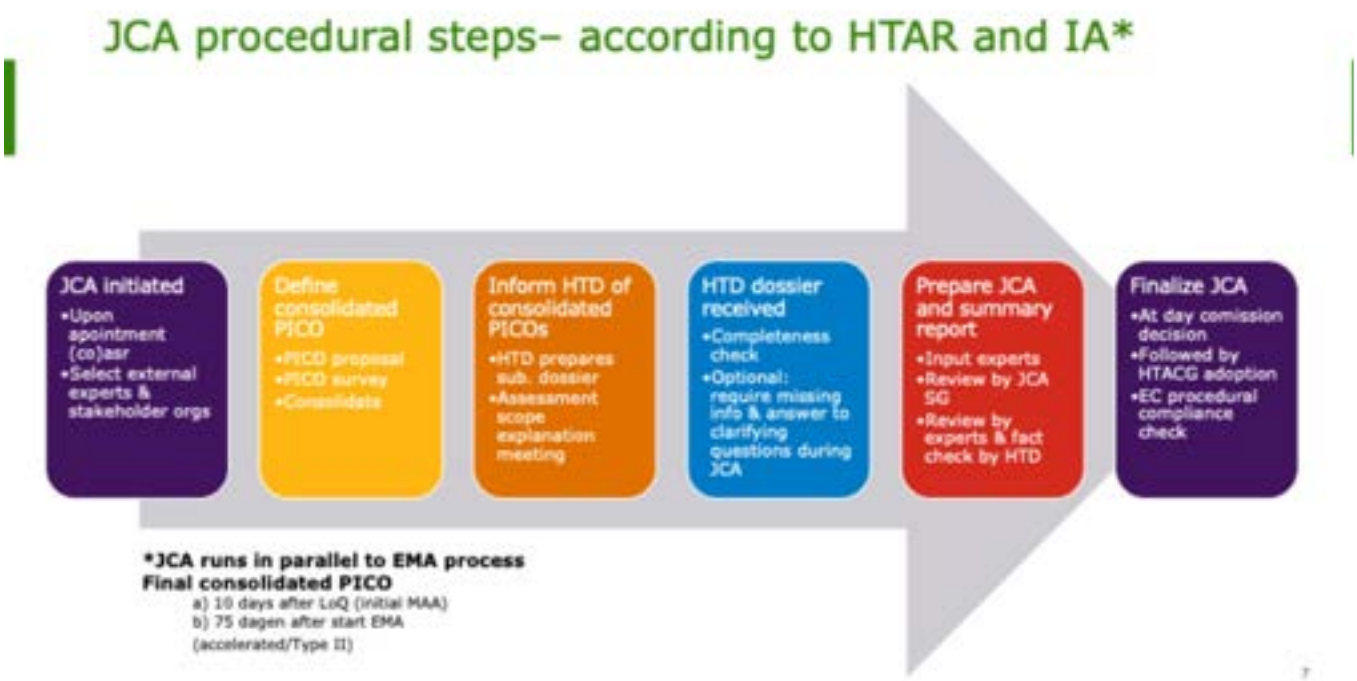
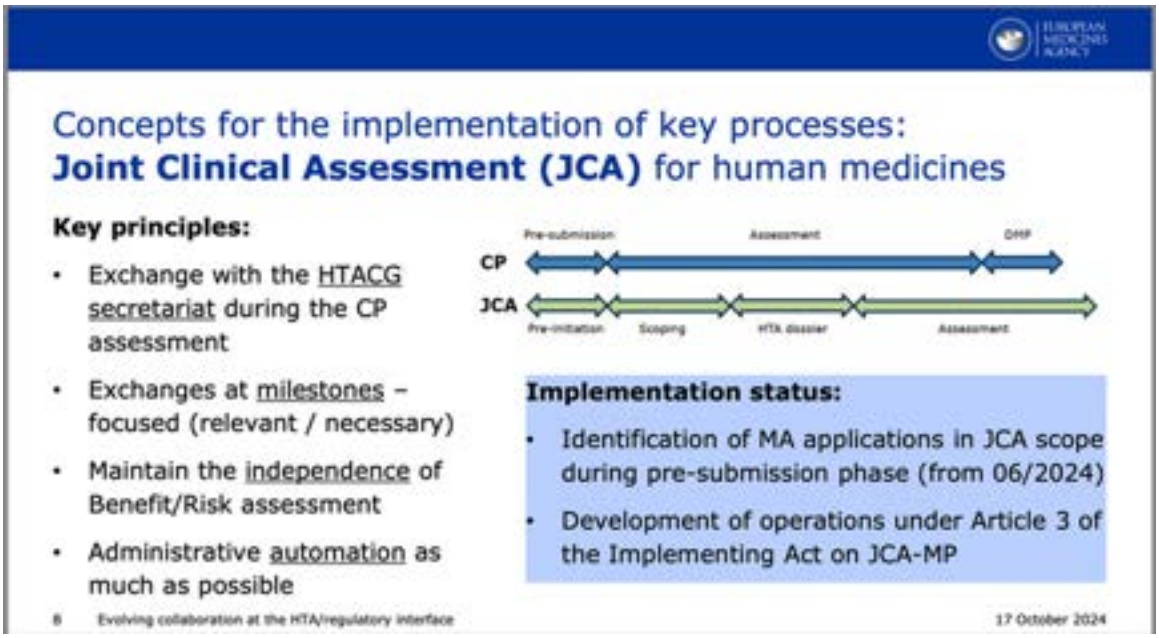
And she made it clear that the regulatory assessment and the HTA will be handled in parallel.



Anne's presentation was complemented by the one given by **Michael Berntgen**.



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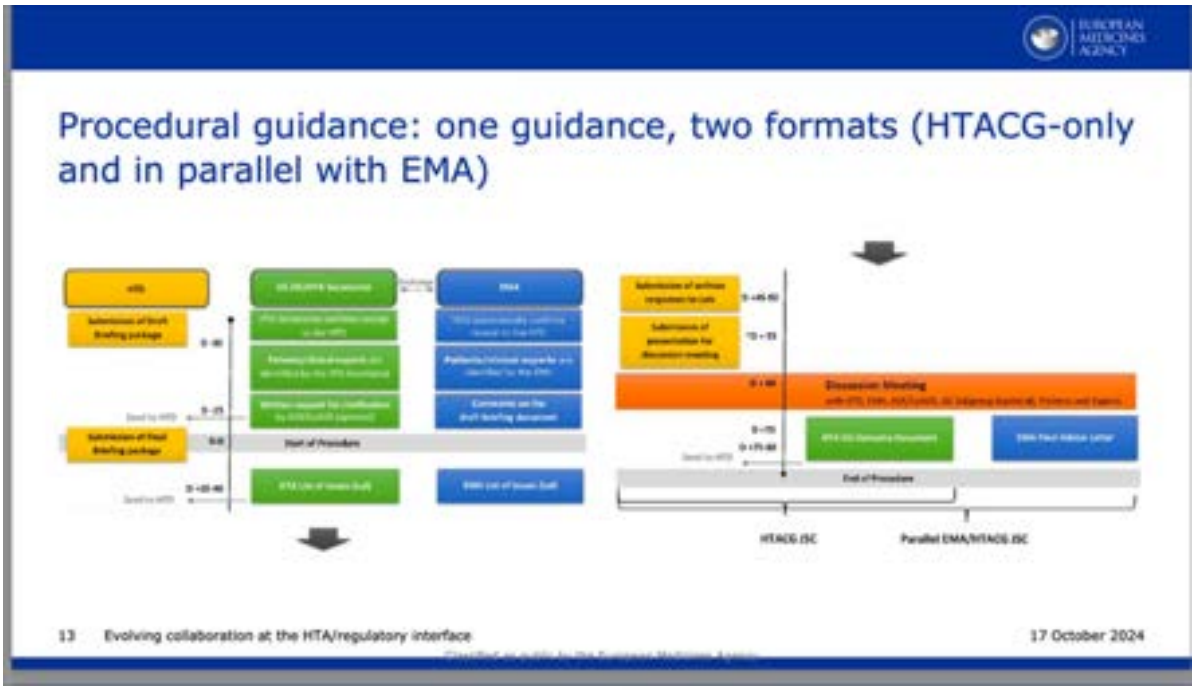
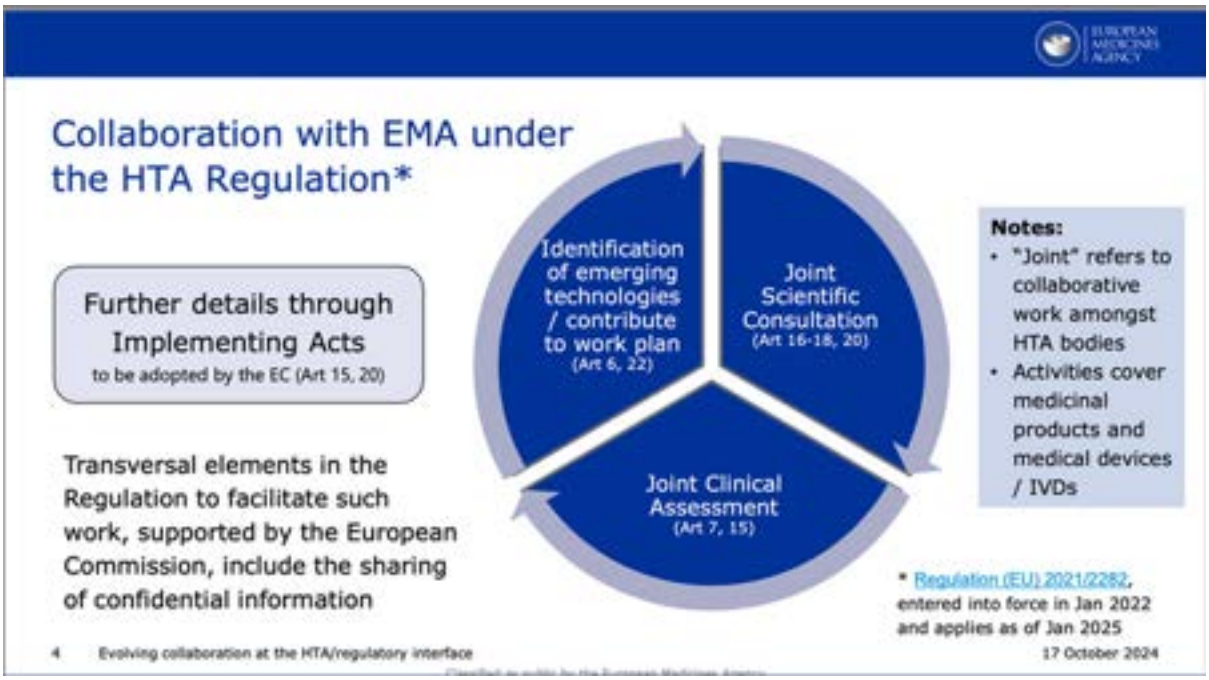


The overall interaction of EMA and HTA is summarised in the following slide:



Both speakers pointed out that the topic is still an evolving one and therefore it is recommended to follow closely EMA and EU-HTA.

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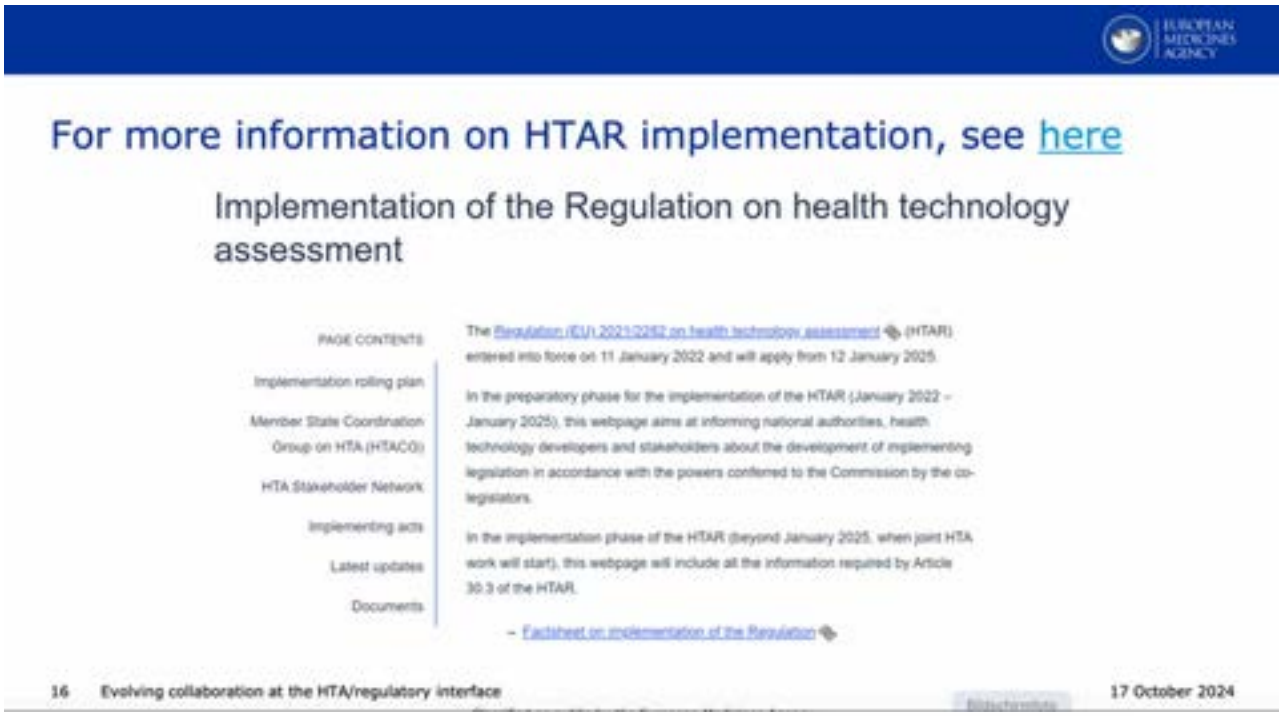

Author: **Birka Lehmann**, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

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Call for Abstract - ICPM 2025

Are you at the forefront of innovation in pharmaceutical medicine? Do you have groundbreaking research, unique insights, or transformative ideas to share? We want to hear from you!

We invite scholars, professionals, and thought leaders to submit their abstracts for ICPM 2025. This is your opportunity to contribute to an inspiring program and present your work to colleagues, experts and interested parties from the global field of pharmaceutical medicine.

Theme: Purpose for Future

Who should participate?

Anyone – from academics to industry and professionals as well as students – is welcome to contribute. Both theoretical and practice-oriented contributions are appreciated.

Important data

- Submission deadline: **December 31, 2024**
- Acceptance feedback: **January 31, 2025**
- Conference: **April 9-11, 2025**

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Abstract Submission Guidelines

- Abstracts may contain a maximum of 200 words.
- Include a clear title, the names of the authors and their affiliation(s).
- Briefly write the purpose, methodology, results and relevance of your work.
- Indicate the take-away for the participants.

Why participate?

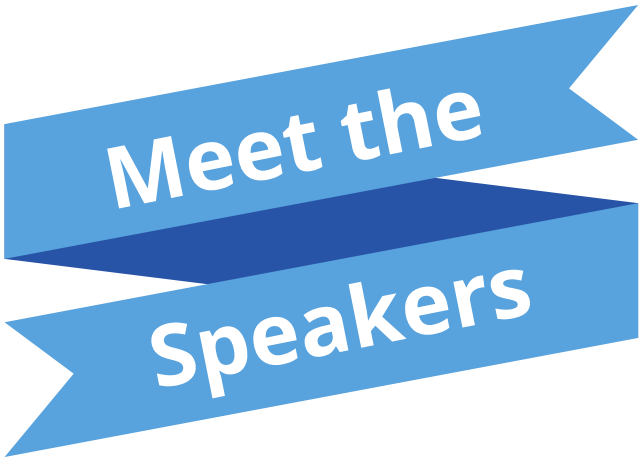
- Share your knowledge and expertise with an interested audience.
- Receive valuable feedback and network with professionals in the field.
- Possibility of publication in the conference proceedings.

How to submit?

Please visit our website (www.icpm2025.com) for detailed submission instructions and criteria.

Do you have any questions? Please feel free to contact us at info@icpm2025.com.

We look forward to receiving your abstract and creating an inspiring program together!



We are thrilled to announce an interesting frist line-up of esteemed speakers from the field of pharmaceutical medicine who have confirmed their participation in ICPM 2025.

These thought leaders, innovators, and experts will bring their wealth of knowledge and experience to the stage, offering insights into the latest advancements, trends, and challenges in pharmaceutical medicine.

Stay tuned as we unveil the full list of speakers on our website. Visit www.icpm2025.com regularly for updates and be the first to discover who will be sharing their knowledge and shaping the future of pharmaceutical medicine at ICPM 2025.

Don't miss this unique opportunity to learn from the best – register today and secure your place in the audience!

ICPM 21ST INTERNATIONAL CONFERENCE ON PHARMACEUTICAL MEDICINE 2025

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

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

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