IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

IFAPP President Message - July 2023

Dear Colleagues,

I would like to update you on the recent IFAPP European Regional Meeting outcomes that took place in the Netherlands on June 29th and 30th.

Let me first sincerely thank our delegates, stakeholders, speakers, and IFAPP Board members for their great contributions to the IFAPP European Regional Meeting dialogue and once more congratulate our NFVG colleagues Ellen Evelaar, Eric Klaver, and our secretary, Caroline van Bruggen, for their extraordinary share of work.

We discussed IFAPP leadership perspectives and reached several goals based on our meeting objectives.

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

In Amsterdam, we debated the content strategy for 2023-2024 with a forward-looking innovation and rejuvenation imperative, being at the brink of a transformational science era, with new technologies blending with traditional medicine, Pharmaceutical Medicine, and medicines.
We reviewed the IFAPP strategic roadmap for the future of the organisation, and I am happy to summarise the key highlights:

- IFAPP emphasis on our Community, Communication, Competencies, and Career Development for our Members in the evolving life sciences domain.
- IFAPP Working Groups to embrace innovation and patients' perspectives.
- IFAPP and NMAs partnerships with academic and professional education organisations to attract younger professionals into our network.
- IFAPP commitment for an inclusive and diverse multidisciplinary Pharmaceutical Medicine future enabled by current leadership for growing next generation IFAPP leaders.
- IFAPP focus on preparing young professionals and upskilling our members for the new era on top of the monthly established IFAPP webinars, by including series of webinars on new frontiers, e.g., Ethics in Genomics Research, Digital Health, Medical Affairs, and Patient-centred evidence and decision making.
- IFAPP TODAY Newsletter upgrade to IFAPP TODAY Journal due to its picks of developments, reports & scientific updates, growing readership, and impact.
- The IFAPP international, interconnected network of National Member Associations, Individual Affiliates, and Stakeholders' joint efforts & collaborative projects on Pharmaceutical Medicine as multifaceted discipline.

The IFAPP European Regional Meeting was an exciting networking experience and a wonderful teamwork with inspiring outcomes that will augment intergenerational continuum, connectivity, and value to members. It was very important that we got to know each other and very reassuring that new colleagues joined spontaneously our Working Groups following their exchange of ideas in the Workshops on June 30th.

I am thrilled by the enthusiastic feedback received from our delegates on how innovation and creativity can set us apart for the future.

It was great engaging with all of you, gifted young, mature and senior colleagues, and I am grateful for the stimulating energy on IFAPP's visionary evolution.

I will keep in touch by sharing more diverse and co-creative approaches from the IFAPP Asian Regional Meeting in Japan at the end of this month.

Sincerely yours,

Varvara (Barbara) Baroutsou
IFAPP President

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Insights from the IFAPP European Meeting 2023

The IFAPP European Meeting 2023 was held in Amsterdam on 29 and 30 June, 4 years after the last one held in Athens in 2019. IFAPP - International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine - was established in 1975 and is a worldwide network made up of National Member Associations and Individual Affiliates in 32 countries.

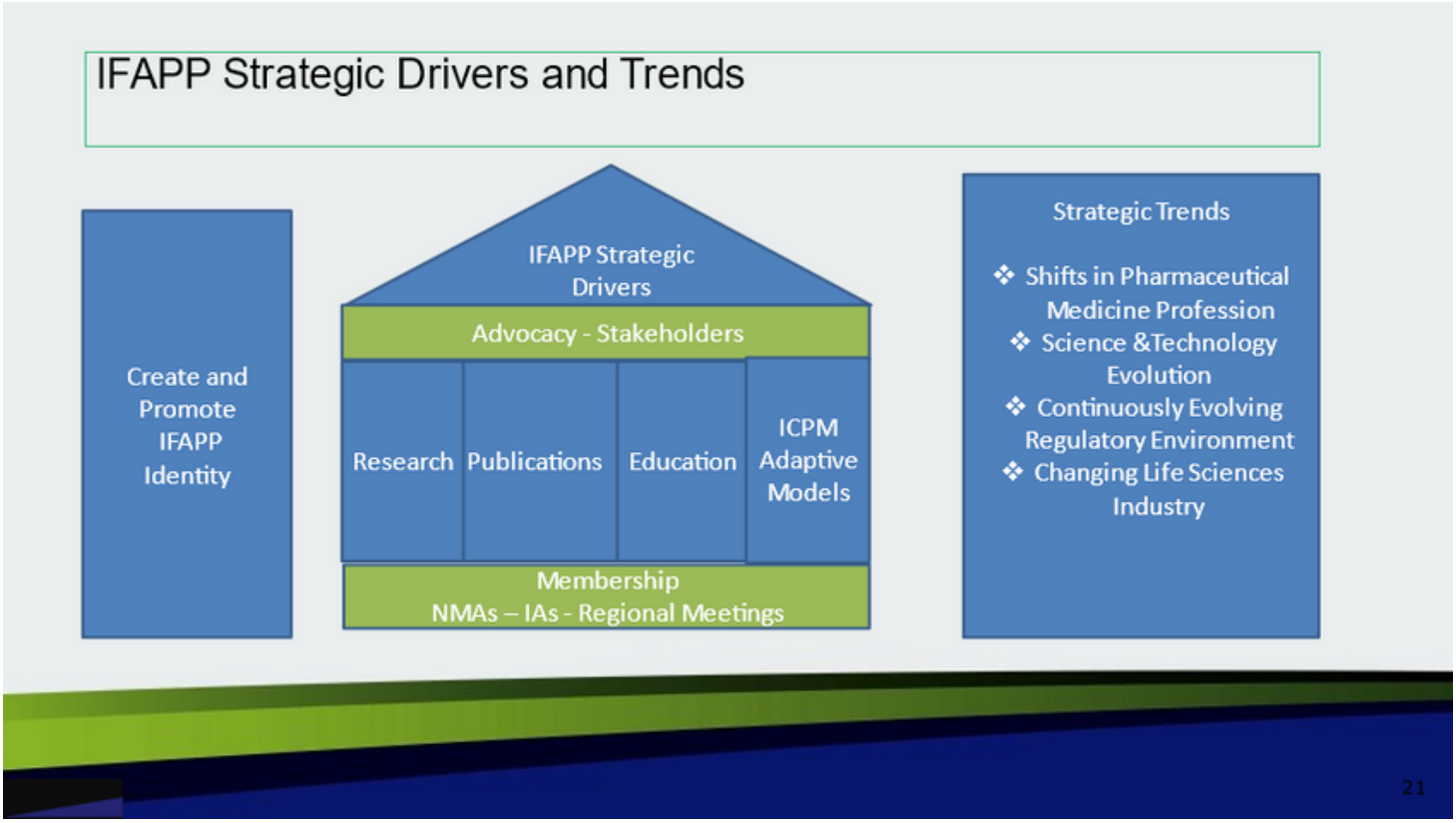
The IFAPP Board of Officers was represented at the meeting by Varvara Baroutsou (Greece, President), Anna Jurczynska (Spain, Secretary), Nikolaos Tsokanas (Greece, Treasurer). Ghazaleh Gouya-Lechner (Austria), Birka Lehmann (Germany), Kotone Matsuyama (Japan), Cordula Landgraf (Switzerland), and Annette Mollet (Switzerland). Furthermore, 15 National Member Associations (NMAs) Delegates of Austria, Belgium, Bulgaria, Czech Republic, Finland, Greece, Hungary, Italy, Ireland, MEAPP, the Netherlands, Portugal, Spain, Sweden, and Switzerland were also present at the meeting (Figure 1).

Figure 1 IFAPP European Meeting 2023, Amsterdam

The objective of the 2023 European meeting, presented at the opening by the President Varvara Baroutsou, emphasised the **positioning of IFAPP as a critical reference for Pharmaceutical Medicine**. The meeting's primary objectives included formulating a strategic roadmap for the organisation's future and implementing impactful measures (Figure 2, next page). This necessitates a strong focus on innovation, strategic thinking, and leadership within the entire IFAPP community. The profound changes that the pharmaceutical sector is experiencing, and more generally all the life sciences, require careful reflection. IFAPP must adeptly and effectively respond to external influences, utilising the collective efforts of national member associations (NMAs), experts and key thought leaders in Pharmaceutical Medicine to anticipate future trends and overcome obstacles. The Amsterdam gathering holds symbolic significance as it prepares the Federation for a journey with a clear direction for a sustainable future. Importantly, this process must embrace an evolutionary approach, preserving continuity and honouring IFAPP's extensive history (1975 - today) and the respective NMAs.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Figure 2. IFAPP Strategic Drivers and Trends



Music is said to begin and end with Bach. The Bach of our associative universe are young people, the new generation of professionals, the future leaders of national associations (NMAs) and IFAPP. Each generation has its own characteristics, its qualities, determined by the time in which they grew up and lived. It will only be through a profound knowledge of human capital that we will be able to welcome it and make the most of it, through a virtuous intergenerational exchange.

A very important role is played by the academic community and professional educational ecosystem. IFAPP is determined to contribute responsibly to harmonising and integrating academic and professional development training, forging partnerships with prestigious universities such as London King's College, the University of Basel, and the PharmaTrain Federation.

Speeches respectively by Ingrid Klingmann, President of PharmaTrain, Prof. Peter Stonier (Centre for Pharmaceutical Medicine Research, Institute of Life Sciences and Medicine, King's College London), Prof. Flic Gabbay (President of the Faculty of Pharmaceutical Medicine), and Annette Mollet (Managing Director ECPM and Head of Education and Training, University of Basel, Switzerland, IFAPP Board Member & Young Professionals Working Group Lead) well described the cooperative will between IFAPP and academia during the Amsterdam meeting. Furthermore, each NMA will evaluate programmes to approach universities, cooperating and implementing campaigns to approach the association community. IFAPP, together with the NMAs, serve as a crucial link between academia and professional domains while playing a vital role in post-academic training.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

It is evident that the incorporation of not only academic knowledge, but also new insights and practical experience is essential in preparing young professionals for the emerging frontiers of the healthcare industry, including Digital Health, Medical Affairs, patient-centred care, and other related areas.

During the meeting, Prof. Kotone Matsuyama (Nippon Medical School, IFAPP Board Member and Ethics Working Group Lead) offered the participants an interesting and debated session on the revision of the Helsinki Declaration, focused on data-driven research. The existence of an IFAPP Working Group dedicated to ethics and founded in 2001, coupled with this initiative, highlights the timeliness and significance of ethical considerations for both the Federation and the broader Pharmaceutical Medicine sector. It underscores the moral imperative of conducting clinical research responsibly and ethically.

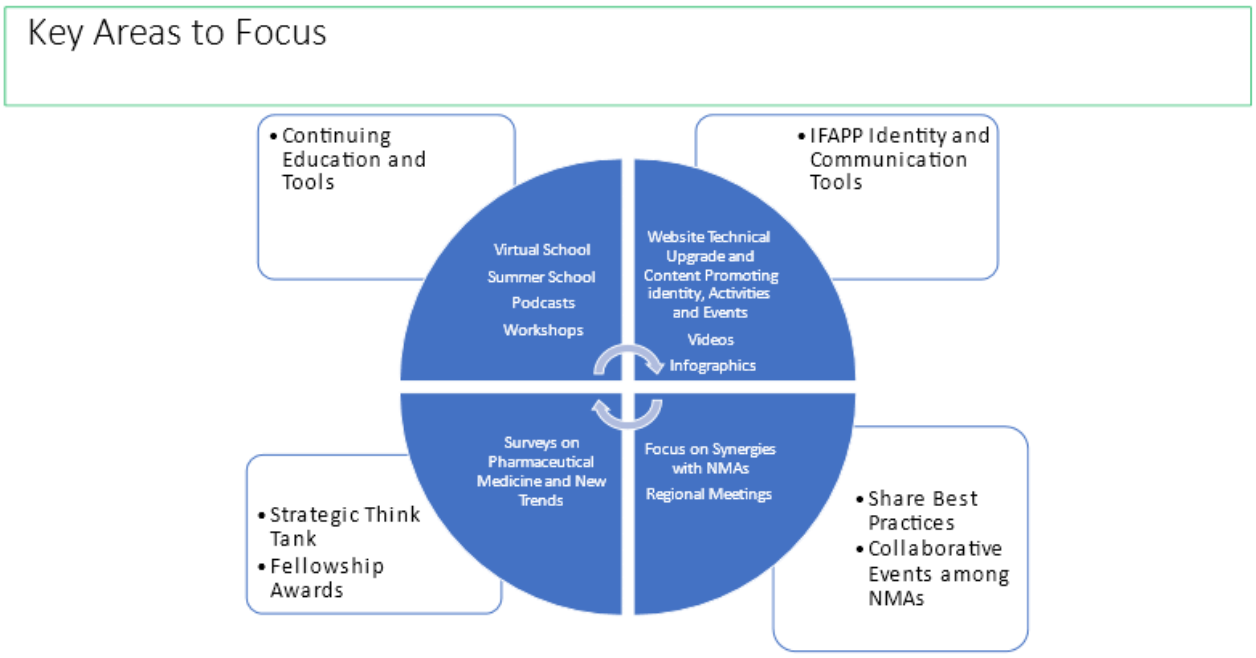
The workshops held during the IFAPP European Meeting 2023 were aimed to facilitate the envisioning and redefinition of the Federation, beginning with the key focal areas (Figure 3).

- IFAPP Profile - Identity, coordinated by Cordula Landgraf
- Career in Pharmaceutical Medicine, coordinated by Annette Mollet
- Emerging Ethical issues in Genomic Research & Digital Medicine, coordinated by Kotone Matsuyama
- Modern Clinical Research, coordinated by Birka Lehmann
- IFAPP TODAY Newsletter: Time for change? coordinated by Ghazaleh Gouya-Lechner

A deep innovative will emerged from all groups, as well as an awareness of the importance of the community of IFAPP and NMAs as the real engine of the Federation.

The key words were: **Community, Communication, Competence, Diversity, Career**.

Figure 3: Key Areas to Focus



IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Another strong sign of renewal of this IFAPP European meeting is the will to create new IFAPP working groups (Innovation, Patient Associations) and partially integrate the existing ones.

We can confidently affirm that IFAPP stands as a significant point of reference for all NMAs. This is particularly crucial in a world that is increasingly interconnected and rapidly evolving. Moreover, IFAPP fosters an inclusive international network, where every member of the NMAs has the opportunity to contribute and grow collectively within the community.

The Amsterdam meeting will be followed by the IFAPP Asian Regional Meeting on 29 July, which will address the topics described here with the same spirit.

Francesco Butti, Boehringer Ingelheim, Head of Development & Clinical Operations, Italy.

Figure 4: IFAPP European Meeting 2023, Amsterdam, meeting in progress.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The Language of the Next Generations – How to Address Them?

We introduced the definitions of the silent generation, the baby-boomers, generation x, y, and z.

The term "silent generation" typically refers to individuals born between the mid-1920s and the early 1940s. They were called the silent generation because they came of age during a time of economic prosperity and often conformed to societal norms rather than challenging them. They prefer to meet and exchange face to face.

Baby boomers, born between 1946 and 1964, primarily grew up experiencing the rise of new technologies and inventions. They prefer to communicate by phone calls.

Generation X refers to individuals born roughly between the mid-1960s and early 1980s. They grew up during a period of significant cultural and technological change, witnessing the rise of personal computers, the internet, and other advancements. They are often characterised as independent, self-reliant and communicate via e-mails.

Generation Y, also known as millennials, generally includes individuals born between the early 1980s and the mid-1990s. This generation came of age during the rapid expansion of the internet and the proliferation of mobile devices. Millennials are often associated with a strong desire for work-life balance, technological fluency, and social consciousness. They exchange via text messages.

Generation Z, also referred to as Gen Z or the iGeneration, typically encompasses individuals born from the late 1990s to the early 2010s. This generation is considered the first to have grown up entirely in the digital age, with smartphones, social media, and constant connectivity being integral parts of their lives. Gen Z is often characterised as tech-savvy, diverse, and socially aware. They communicate via text messages and social media.

A mentimeter survey among the participants of the IFAPP European Regional Meeting revealed the following:

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

It is important for IFAPP to attract young members and professionals by supporting and mentoring the young generation:

- mentoring/supporting career opportunities
- offering continuing education => Education and Certification Working Group (ECWG) of IFAPP and collaboration with PharmaTrain
- career days => look for local events at universities, etc.
- ideas and suggestions are welcome, please approach us.

During the Regional Meeting in Amsterdam on 29 & 30 June 2023 we extensively discussed with the Young Professionals Working Group ways of how to attract more young professionals to our community. We agreed to focus on mentoring and supporting young professionals through industry professionals with many years of experience. Calling all young professionals in the pharma industry!

In addition, IFAPP offers continuous education via the Education and Certification Working Group, several webinars and other educational activities in collaboration with PharmaTrain.
National Member Associations do organise career days in collaboration with local universities and pharmaceutical companies.
The Working Group of Young Professionals is always seeking new ideas and suggestions. Please do get in contact with the young professionals' team for further discussions and new ways of collaborating.
Do you want mentoring and support by top professionals in the industry? IFAPP is your place to be!
Would you like to have the opportunity to continue learning and expand your knowledge of the field? IFAPP is where you need to be!
Do you want to take part in career days in various venues and locations? Come join the IFAPP family!
Do you have special ideas and suggestions? IFAPP is waiting to hear from you!

Authors for the IFAPP Young Professionals Working Group:
Annette Mollet, ECPM University of Basel, and **Nikos Tsokanas**, Bayer AG

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Modern Clinical Research (DCT, RWD, AI, EU CTR & Patient Centricity)

Workshop at the IFAPP European Regional Meeting held in Amsterdam on 30 June 2023

Participants: Tatyana Benisheva, Simone Breitkopf, Eric Klaver, Koen Raeymaekers,
Chair: Birka Lehmann

The outcome of the discussion was split in three topics:

1. Focusing the topics of the webinars on 'hot topics'
a) Overall agreement was reached to try to focus on webinar topics like
- Patient Centricity and Decentralisation
- Real World Evidence/Real World Data
- AI in clinical research

It was discussed whether it will be possible to develop a series of 3-4 webinars and presenting the different topics under an overarching umbrella like
'News in clinical trials' or 'Decentralised clinical trials'

b) To present the IFAPP working groups in webinars to increase the awareness of IFAPP tasks and duties

2. Improvement of the awareness of IFAPP webinars for the members
a) To increase the co-operation of IFAPP and the National Member Associations (NMAs) by improving the information on webinars conducted by NMAs and IFAPP, e.g., to make the IFAPP course marketplace more prominent.
b) To improve the possibility to cross-reference between NMA courses

3. Technical and administrative improvements
a) Publication of IFAPP webinars well in advance
b) Register for participation and to receive the webinar on demand
c) Fees for member participants and non-members (slicing scale)
d) IFAPP certificates for attendance

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

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

IFAPP Regional Meeting Amsterdam – Workshop on IFAPP's Profile and Identity

"Without knowing where you are sailing to, no wind will be favourable" according to the Roman philosopher Seneca.

Inspired by the great philosopher, we* reflected on the profile and identity of IFAPP. We focused on three elements that are key for a coherent and compelling identity:

Purpose → Why do we exist?
Value → What do we offer? For whom?
Culture → How do we operate?

We started off with the almost philosophical question of why IFAPP exists. In our view, IFAPP is our professional home, our "nest", where all members feel comfortable. Altogether, IFAPP is a community where people want to belong to and feel welcome. Consequently, the focus should be on the people, not on the organisation itself. We should be perceived as a community of like-minded professionals that communicates from the perspective of its members.

From previous discussions at the meeting, we clearly identified the need to attract younger professionals, the next generation. With this target audience in mind, we came up with three concrete proposals what IFAPP should offer:

- Career development and pathways possibilities
- A trustful information hub/platform to exchange and share knowledge easily
- A mentorship programme

To create a strong culture that helps attract like-minded individuals IFAPP should follow an inclusive, open-door policy with transparent communication and a focus on (inter)-connectivity.

This is where we want to sail to. Cast off!

*Participants of the workshop:
Kata Mazalin, Onthatile Serehete, Peter Stonier, Cordula Landgraf (Chair)

Cordula Landgraf, PharmD
IFAPP Board of Officers member and Chair of External Affairs Working Group

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

1st IFAPP Asian Regional Meeting 2023

Join us!! "IFAPP Asian-Pacific Regional Meeting" on 29 July 2023

Join us for the Asian-Pacific Regional Meeting planned to take place on 29 July.
The regional meeting will focus on current topics and issues in Pharmaceutical Medicine in various countries in the region. The Asian Meeting will be positioned as a Regional IFAPP Meeting and will hold discussions on Pharmaceutical Medicine in countries that have national member associations (NMAs) in Asia, i.e., Japan, Korea, the Philippines, Australia, and Singapore.

Recent Medical Affairs activities in the Asia-Pacific region have their regional characteristics, with backgrounds based on international drug development and the medical situation in each country.

The current situation and future prospects will be discussed based on input from each member organisation. We also need education and certification for Medical Affairs professionals (not only Medical Science Liaisons (MSLs) but Medical Directors, for example) and a capabilities framework should be established to develop well-qualified MA professionals with certification accredited by established authorities.

Our Asian-Pacific colleagues can also guide us basics of Health Technology Assessments (HTA), upon which we can adapt to the national healthcare system to make our products accountable to society. The Australian NMA colleagues have a tight relation to the Medical Affairs Professional Society (MAPS). Hope to collaborate with all other IFAPP NMAs based on the current situation in Asian-Pacific countries.

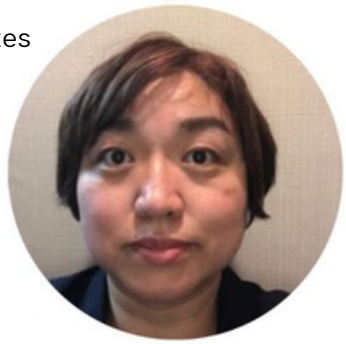
IFAPP TODAY
The Global Pharmaceutical Medicine Journal

This meeting is held as part of the annual congress of JAPhMed (Japanese NMA).

Venue: Zoom meeting
Date: **29 July 2023 (Sat), at 14:40-15:40 (Tokyo time)**

Click here to access the meeting.
Meeting ID：836 6793 3279
Passcode： 530163

The proposed agenda will read as follows:
1) Introduction of IFAPP in general
2) Introduction of best practices in Medical Affairs from each NMA/Individual Affiliates
3) Expectations of IFAPP (participants from Asian NMAs/Individual Affiliates)
4) Discussion
5) Any other proposals for discussion



Please try to participate in the Asian Regional Meeting as above.

Kotone Matsuyama
Professor, Department of Health Policy and Management
Deputy Director, Center for Strategic Research Initiative, Nippon Medical School
Director, Board Certified Member of JAPhMed
Standing Officer of Ethics WG, IFAPP

The Research Innovation Circle

Digitisation and utilisation of health data, aiming to enable personalised medicine.

GPMed
GESELLSCHAFT FÜR PHARMAZEUTISCHE MEDIZIN E.V.

GPMed's new kid on the block - the Research Innovation Circle (RIC) - is a distinguished forum established in 2022, specifically designed to explore novel approaches in health research. Committed to advancing the utilisation of real-world data in healthcare research, the RIC's accomplished team focuses on essential requirements for improved real-world data utilisation, adaptive study designs, platform studies, and studies involving medical devices, including software as medical devices (EU 2017/745 MDR and EU 2017/746 IVDR).

The Research Innovation Circle is led by Tanja Stamm and Veronika Mikl, who bring a wealth of expertise and experience from academia and industry to the table (see bios below).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Comprising eight outstanding representatives from academic research, contract research organisations (CROs), and research departments of the pharmaceutical industry, the RIC members are personally nominated by the esteemed GPMed board. They convene six times annually to foster productive exchanges and robust discussions on forward-thinking innovations within the research domain.

The outcomes of these RIC meetings serve as the bedrock for subsequent initiatives, including GPMed training events, scientific publications (such as the notable JMIR Quality for RWD, https://doi.org/10.2196/34204), as well as GPMed statements or positions on pertinent matters. These outcomes are thoughtfully shared and deliberated upon with stakeholders from the realms of science, politics, and regulatory authorities, ultimately driving sustainable improvements in the framework conditions for applied clinical research in Austria.

Tanja Stamm (Univ.-Prof. Mag. Dr. Tanja Stamm, PhD, MSc, MBA)

Tanja Stamm is a highly accomplished professional with a strong background in health research and innovation. With an extensive track record in the field, Tanja has demonstrated exceptional leadership skills and a keen understanding of the intricacies of research methodologies. Her expertise lies in the areas of data utilisation, digital health, and personalised medicine. Tanja's passion for driving advancements in healthcare research is evident in her commitment to the Research Innovation Circle, where she plays a pivotal role in shaping its strategic direction.

Tanja Stamm is a Full Professor and Head of the Institute for Outcomes Research, as well as Deputy Director of the Centre for Medical Data Science at the Medical University of Vienna, Austria. Since January 2022, Tanja additionally leads the Ludwig Boltzmann Institute for Arthritis and Rehabilitation. Her research focuses on Patient-Reported Outcomes, Value-Based Care, Digital Health, Musculoskeletal Diseases, and Real-World Data. Tanja Stamm combines clinical expertise with other advanced research skills and professional competence in data science. She has pioneered work in various medical fields, such as rheumatology, musculoskeletal health, rehabilitation, public health, diabetes, dietetics, and oral health. She has also been involved in the development of complex multi-centre drug studies and registries, including their digital infrastructure and patient-centred approach. Until June 2020, Tanja Stamm was Vice President of the European League Against Rheumatism. Since 2020, she chairs the outcomes task force of the European University Hospital Alliance, a network of 9 leading university hospitals in Europe (https://www.euhalliance.eu/) and co-leads the Innovative Medicines Initiative (IMI) Health Outcomes Observatories H2O Project (https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0146).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Mag. (FH) **Veronika Elisabeth Mikl**

As a board member of the Society for Pharmaceutical Medicine (GPMed) and co-chair of the Research Innovation Circle (RIC), Veronika Mikl passionately supports GPMed's ambitions to promote education and training activities so that representatives of academic, pharmaceutical, and medical technology research departments can improve the quality of clinical research in Austria.

Veronika Mikl joined the GPMed board in March 2023 and has been employed since 2012 at Roche in Austria. At Roche she is leading and contributing to strategic initiatives in Market Access, Governmental Affairs and Policy Chapters. Since 2019 she has overseen Market Access & Health Policy activities around Personalised Healthcare & Digital Health.

Before her career within Roche, she worked as Consultant in the specialised Austrian healthcare agency PERI Consulting where she collaborated intensively with researchers, physician associations, and stakeholders to tackle key issues along patient journeys in the Austrian health system.
Veronika Mikl completed her Marketing & Sales master's degree at the CAMPUS|02 University of Applied Sciences in Graz in 2005 and started her career in the health sector in 2006.

Contacts:
veronika.mikl@roche.com
tanja.stamm@meduniwien.ac.at

Report from the IFAPP Webinar on 8 June 2023

HTA REQUIREMENTS IN RELATION TO THE EU REGULATION
A German Perspective

Dr. Stephanie Said, Scientific Advisor and Senior Project Manager, Gemeinsamer Bundesausschuss (G-BA), Head of EUnetHTA 21 JSC Secretariat, Chair of the HTA Coordination group, subgroup on Joint Scientific Consultations (JSC), presented the topic.

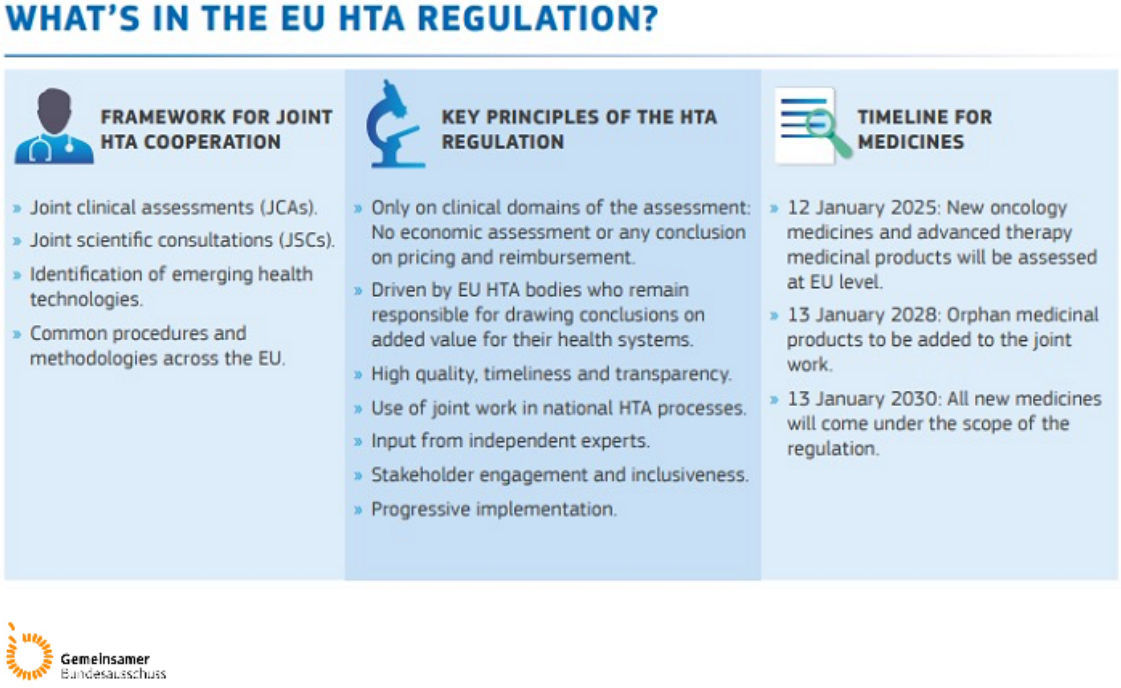
The Regulation (EU) 2021/2282 on health technology assessment (HTAR) contributes to improving the availability for EU patients of innovative technologies in the area of health, such as medicines and certain medical devices. It ensures an efficient use of resources and strengthens the quality of HTA across the European Union.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

It provides a transparent and inclusive framework by establishing a Coordination Group of HTA national or regional authorities, a stakeholder network and by laying down rules on the involvement in joint clinical assessments and joint scientific consultations of patients, clinical experts, and other relevant experts.
The HTAR will also reduce duplication of efforts for national HTA authorities and industry, facilitate business predictability and ensure the long-term sustainability of EU HTA cooperation.

EU-HTA Regulation (HTAR)

Source: EC fact sheet - Implementing the EU Health Technology Assessment Regulation (europa.eu)



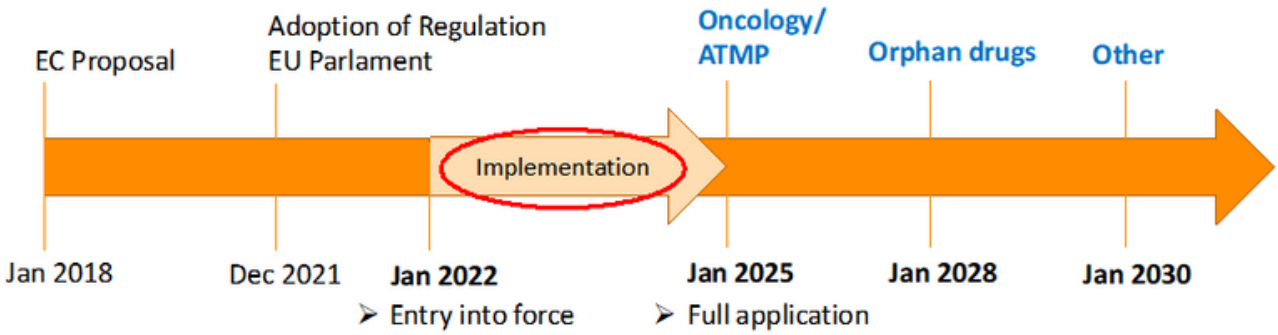
The HTAR will be applicable for some classes of medicinal products from January 2025 and fully applicable from January 2030 for all medicinal products:

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

EU-HTA Regulation aims and timeline

Main aims of the EU-HTA Regulation:

- Improve the availability of innovative health technologies for EU patients
- Avoiding duplication of work in the Member States (MS)
- Sustainability of joint European HTA work



Gemeinsamer Bundesausschuss

The new HTA procedures are split in the joint scientific consultation procedure and the joint clinical assessment.

HTA key products

Joint Scientific Consultation (JSC)	Joint Clinical Assessment (JCA)
DEFINITION	
Scientific advice provided jointly by HTA bodies to manufacturers on the clinical development. Can be in parallel with regulators	Joint HTA reports produced by multiple European Member States, focussing on the clinical domains
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

Gemeinsamer Bundesausschuss

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The key challenges are:

JSC challenges

- **Number of consultations under the regulation still open**
  - Should be in accordance with demand, capacities for European consultations might be limited but need to be ensured to meet principle of "fair and equal treatment"
  - Evaluation envisaged as to whether a fee-paying mechanism should be introduced
- **Due to strict selection criteria (clinical trial in planning phase), no European consultation is possible before submission of HTA dossier ("pre-submission" consultation)**
  - However, these consultations currently make up the larger percentage of G-BA consultations
  - Does not enable for consultation on PICO for dossier preparation
- **Bridging the interim phase after the end of EUnetHTA 21 (October 2023) until the full application of the EU-HTA Regulation from January 2025:**
  - EMA/HTAb Scientific Advice – official announcement will follow in June 2023

Gemeinsamer Bundesausschuss

Challenges JCA on scoping/PICO

Challenges in PICO consolidation

- Goal: Meeting Member States (MS) requirements while minimising the number of PICOs
  - Population: Subpopulations vs. subgroup analyses
  - Intervention: According to the SmPC
  - Comparator:
    - Linkage "AND"/"OR"
    - Level of detail (e.g. "standard of care", "chemotherapy")
  - Outcome: Listing of all submitted endpoints
- Overall different terms and definitions ("patient-specific therapy") across MS

Gemeinsamer Bundesausschuss

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Still:

Important points to consider

- No different assessment standards in the assessment with/without EU JCA report as procedures will run in parallel at least until 2030
- Inclusion of the national PICO for the EU JCA dossier and report
- Completeness of the data provided by the HTD
- Evaluation on refinement of national law in progress, especially in terms of timing

- **Remit and responsibilities of the G-BA and also main procedural steps of the national AMNOG process remain the same!**
- **Value judgement is made by the G-BA when determining the additional benefit (JCA report does not give recommendations on added value or reimbursement)**
- **There are open questions remaining on methodological and procedural items that will be handled by the HTA Coordination group and its subgroups during the implementation of the HTAR**

Gemeinsamer Bundesausschuss

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

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

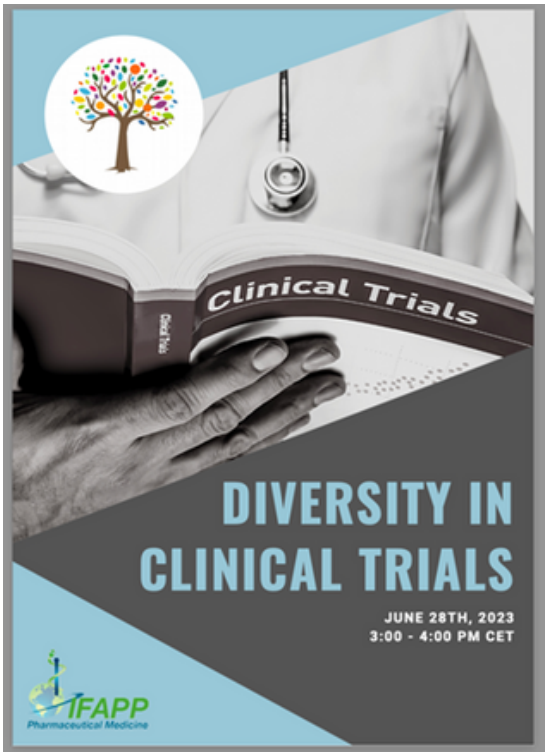
Report from the IFAPP Webinar on 28 June 2023

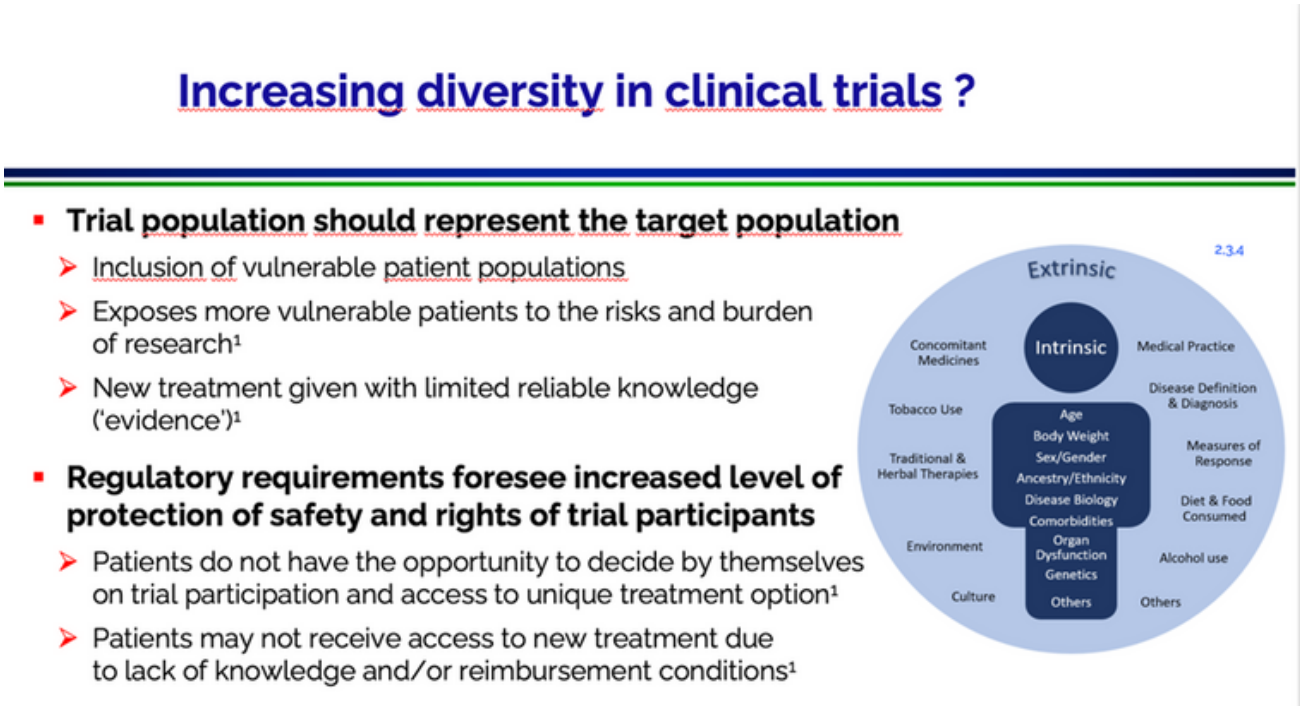
Diversity in Clinical Trials

The new EU Regulation on Clinical Trials aims at facilitating diversity by defining the ethical and legal conditions for enrolling vulnerable patient groups like minors and pregnant or breastfeeding women. But the request for more diversity goes beyond this.

It is important that subjects participating in clinical trials truly represent the complete target population. However, there is the methodological need for standardisation of in- and exclusion criteria as well as the study conditions to reduce data variability and ultimately the required number of enrolled patients to be able to show the true difference between two treatments.

It's essential that clinical trials include people with diverse characteristics in ethnicity, genome, age, sex, and sexual orientation, so that all communities can benefit from scientific advances as soon as possible.





IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Patient groups

Healthy subjects: all genders, all age groups including advanced ages!

Symptomatic subjects, e.g., impaired liver or kidney function

Patients: all genders, all age groups, different stages of disease where appropriate

That means:

Children pre-term to end of 17 years of age, pregnant and breast-feeding women, patients incapable of giving informed consent, patients in emergency situations.

What are the barriers to include specific patient groups?

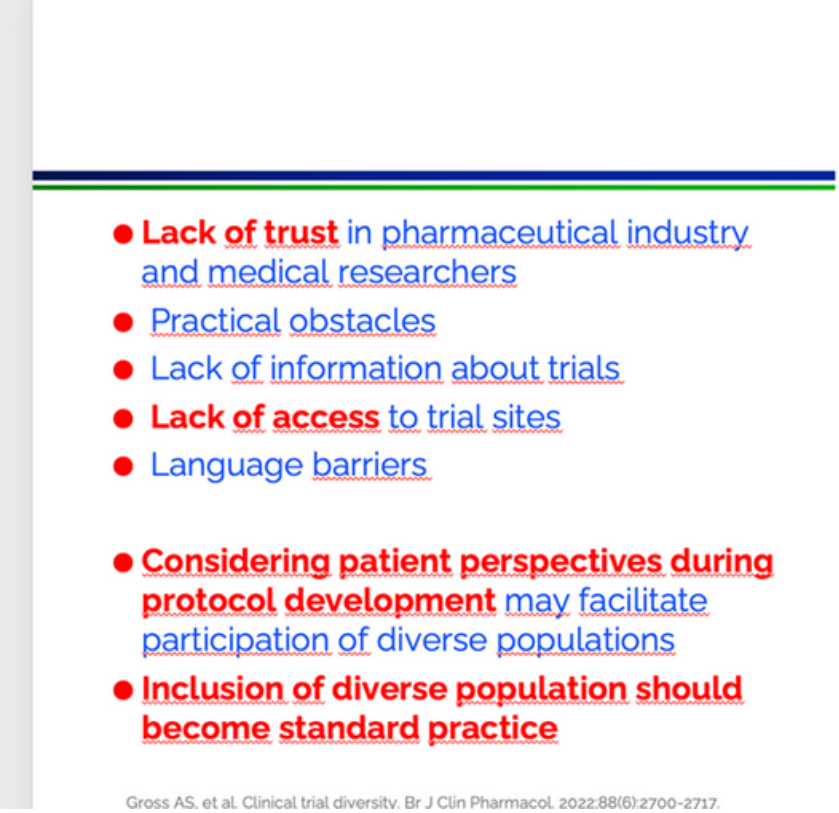


TABLE 2 Barriers to demographically diverse and clinically relevant clinical trial enrolment in relation to the participants, clinical trial sites and the Sponsor/Academic Investigator

Barriers		
Participants	**Clinical trial sites**	**Sponsor/academic investigator**
Lack of trust in pharmaceutical industry and medical researchers, and fears of exploitation	Limited commitment and effort	Limited commitment and effort
Practical obstacles to participation and inconvenience	Unconscious bias	Low willingness to work with research naïve sites/ investigators
Lack of awareness/ information about disease and trials	Lack of culturally or racially/ethnically diverse staff	Limited understanding of what a potential participant wants or needs to enrol
Low health literacy	Lack of effective referral basis/ health care providers fear of losing patient	Negative attitudes about minority willingness
Lack of access to clinical trial sites	Lack of community engagement	Assumptions that diverse enrolment would conflict with trial efficiency
Language barriers	Lack of knowledge of cultural differences leading to ineffective communication	Costs and potential time delays associated with engagement

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

To increase the diversity in clinical trials is an opportunity to improve insight:

- Concerted effort is required to characterise further the factors influencing inter-individual and regional differences
- Challenges to participation in clinical trials remain, and certain groups continue to be underrepresented in development programmes
- Notion of intrinsic and extrinsic sources of variability has been embedded into different regulatory guidelines
- Increasing the diversity of clinical trial populations to reflect the patient population should be best practice in clinical drug development

Kerstin Breithaupt-Grögler (MD, PhD) Board Certified Specialist in Clinical Pharmacology, AGAH Regent (Association of Applied Human Pharmacology, AGAH e.V.), AGAH Delegate to EUFEMED
Ingrid Klingmann (MD, PhD) President, PharmaTrain Chairman, EFGCP Chairman of the Board, EUFEMED
Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

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), Varvara Baroutsou, Brigitte Franke-Bray, Francesco Butti, 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.

Follow us on: