IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

The only international organisation for everyone involved in Pharmaceutical Medicine

THIS ISSUE:

New Year IFAPP President Message

Dear IFAPP Members,

Let me start by sharing my best wishes for a peaceful year that will grant us greater balance and hope after a dramatic 2022 experience post the global pandemic, the outbreak of war in Europe, the climate change, the political and economic turmoil.

My first year of presidency at IFAPP coincides with an important stage for our Federation; one where we begin a new strategic plan to guide our goals. In parallel the start of a new year is always an excellent time for reflection and I would like to take this opportunity to briefly look back at some of IFAPP's achievements in 2022, and to highlight some of the activities and opportunities coming up in the next months.

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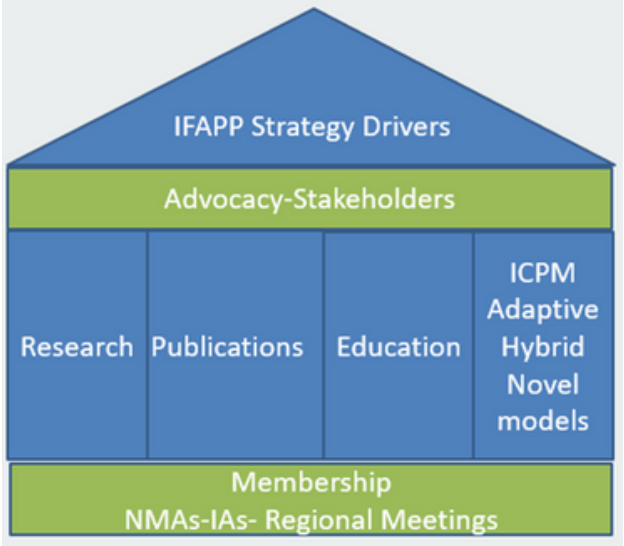
The year of 2022 was a successful year: We had the great pleasure of holding the 20th International Conference of Pharmaceutical Medicine (ICPM) in Athens in October with participants from 27 countries and 5 continents joining our vivid discussions on “What Lies ahead in Pharmaceutical Medicine”. During 2022 we welcomed two new National Member Associations, Middle East & Africa Pharmaceutical Medicine Professionals - MEAPP and Nigeria – PPAN, and several new Individual Affiliates.

The IFAPP Education and Certification WG shaped a framework and guide to steer our educational activities including a programme for scheduled webinars throughout 2023. The IFAPP Ethics WG published two important scientific papers, while the IFAPP External Affairs WG redefined the stakeholders’ network and evaluated potential new collaborations. The IFAPP TODAY Newsletter, under the leadership of the IFAPP Communication WG, excelled in disseminating current developments in our community, and last but not least IFAPP Young Professionals WG is gearing up as shown during ICPM 2022.

The IFAPP strategic plan for 2023-2024 will be rolled out early this year as depicted below, reflecting the overarching areas of our mission and vision. Each of the pillars offers separate but interrelated goals and objectives relevant for our scope.



As a member-focused Federation, input from our members is essential. We currently invite all to contribute emerging trends that you deem impactful for Pharmaceutical Medicine, for our members, for patients and public involvement. This is a valuable opportunity for a future evolution of IFAPP.

Your insights will feed into our strategic plan and contribute to design innovative educational offerings of excellence and relevance for our Members (NMAs and IAs).

I encourage you to submit your needs and ideas for updating or upgrading our strategic curricular planning via email to the attention of the IFAPP Secretary:
Anna Jurczynska: anna.jurczynska@ifapp.org.

In addition, please mark your calendar for our upcoming European Union Clinical Trials Regulation - EU CTR training on March 1-2, 2023 and stay tuned for more that will follow during this year.

We look forward to boosting a culture of responsiveness to the educational and professional goals needs of our broader community by building on our core values and areas of specialty strengths.

Varvara (Barbara) Baroutsou
IFAPP President

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New Board in the Spanish Association (AMIFE)

During the General Assembly held in Madrid (Spain) on 23 November 2022, and following its Constitution, the new Board of the Spanish Association of Pharmaceutical Medicine, AMIFE, was elected as follows:

Dr Isabel Sanchez-Magro, Medical Director, Merck, stepped down after two years in her role as President of AMIFE.
Dr Susana Gomez-Lus Centelles, Medical & Market Access Director, Lundbeck, who acted as Vice-President during the last two years, was ratified as the new President.
Dr Beatriz Perez Sanz, Medical Director, Roche was elected as a new Vice-President.

Other members of the Board include:
Secretary: **Yolanda Peñuela Argudo**, Janssen Cilag
Vice-Secretary: **Monica Rojo Abril**, Grünenthal
Treasurer: **Lorena Secades Hortal**, TFS Health Science
Vice-Treasurer: **Silvia Corretge Conte**, Boehringer Ingelheim
Other members (re-confirmed): **Anna Jurczynska** (Anmar) and **Antonio Gonzalez** (Sanofi)

Isabel, Past President and Susana, new President of AMIFE

Susana Gomez-Lus Centelles, Medical & Market Access Director, Lundbeck Iberia. Physician, with more than 20 years of professional experience in the pharmaceutical Industry.

Susana says: Science is my passion and the mystery of the brain my dedication. I am highly committed to improve the way we help patients. My purpose within the pharmaceutical industry is to inspire others by sharing a common vision. As a member of my team, I try to create an environment that allows for positive group interaction, that will help us facing daily challenges.

Beatriz Perez Sanz, Country Medical Director Roche Farma Spain/Woman in science, physician & haematologist but also developing a career in a pharmaceutical company.

Beatriz says: My best daily fuel is working aligned with my purpose and values to impact positively my partners, the organisation and ultimately our patients. More than 10 years of experience in the pharmaceutical industry in various medical roles. Passionate about my job and how the medical community can continue adding impactful value to the society.

Anna Jurczynska, PhD, MBA
IFAPP Board of Officer Secretary and AMIFE Delegate

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The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP)

MEAPP is a professional membership not-for-profit with a mission to enable all pharmaceutical medicine professionals in the Middle East to gain accredited qualifications, skills, knowledge and experience to elevate healthcare standards and become ambassadors for excellence within Pharmaceutical Medicine. Its goal is to achieve "a world of global equal healthcare practices, without disparity, where effective and affordable medicines are available for all patients everywhere."

The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP) was established in 2021 to introduce and enhance the new medical specialty in the Middle East and develop education standards and certification. MEAPP is currently working with FPM Global to promote the specialty to a new audience in the region.

The aim of MEAPP is to provide educational lectures, webinars, symposiums, workshops on clinical trials and drug development to pharmaceutical medicine professionals, government personnel and academics. It will work in collaboration with bodies such as the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom (FPM) and King's College London to achieve this aim.

MEAPP was recently in Cairo, Egypt, by invitation from the National Research Centre (NRC) and the University of Alexandria CTU and in collaboration with the British Council to promote Pharmaceutical Medicine, and to play a role in creating a platform of competent scientists capable of developing innovative medicine to promote better healthcare in the Middle East region. The public is the ultimate beneficiary of safe and affordable medicines.

Presently, MEAPP is preparing for the first Middle East International Conference on Pharmaceutical Medicine in Q1 2023, in Cairo, Egypt.

During the recent ICPM 2022 in Athens, Greece, the application of MEAPP to become member of IFAPP (National Member Association; NMA) was ratified by all the Delegates of the National Member Associations, to announce the beginning of collaboration between IFAPP and MEAPP organisations.

Dr Assem el Baghdady, MD, MFPM, GFMD – President & Co-founder
Dr Yasser el Baghdady, MB BCh, MFPM, MSc, MBA – CEO & Co-founder
Miss Malak Hassouna – Office Manager - Cairo HQ

Assem (left) and Yasser el Baghdady

The MEAPP Founders

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Assem S el Baghdady MD GFMD MFPM (Dist) is a Senior Lecturer in Pharmaceutical Medicine at King's College London, with over 20 years of experience in medicines development reflected in founding of AlphaBeta Pharma, a drug development consultancy in 2007.

Dr el Baghdady was awarded Membership-by-Distinction by the Faculty of Pharmaceutical Medicine for his contributions to the field of pharmaceutical medicine in 2019, and he also holds the position of Board Director Trustee in the Faculty, Educational Supervisor and Revalidation Appraiser for GMC revalidation.

Assem graduated in medicine from Ain-Shams University, Egypt and continued his research and training in neurology at the Academic Department of Clinical Neurology and Cognitive Psychology at the University of Sheffield. He is a former visiting lecturer of Clinical Drug Development at Surrey University, UK and a Senior Clinical Research Fellow at the University of East Anglia, UK.

He previously held several senior executive roles concerning R&D and Medical Affairs within various pharmaceutical and biotech companies.

His interests are mainly in the Middle East and Far-East regions concerning advancement of the science and practice of Pharmaceutical Medicine and promoting high standard education through founding The Middle East Association for the Pharmaceutical Medicine Professionals – MEAPP – a UK-based not-for-profit where he serves as the first President, and in the field of intellectual property and technology transfers through his capacity as Head of the Innovation and Technology Support Office (ITSO) at the University of San Augustin, Iloilo, Philippines and a visiting Professor at the University of San Paul, Manila, Philippines.

Yasser S el Baghdady MD MSc MBA MFPM is a qualified pharmaceutical physician, with an MD from Cairo-Egypt, and MSc in pharmaceutical medicine from the University of Surrey, UK and MBA from Thames Valley University, UK. He is a member of the Faculty of Pharmaceutical Medicine and also a member of the FPM Global Forum Committee and the FPM Membership Committee.
Yasser has more than twenty years of experience in CVS & metabolism, respiratory drug development and orphan indications, from pre-clinical and first-in-human phase through to registration and post-marketing LCM, he held different positions with various responsibilities working for multinational pharma like GSK and Novartis, as well as biotech pharma like United Therapeutics.
Yasser is a co-founder of AlphaBeta Pharma (2007), a medicine development consultancy partnership that provides consultancy services to biotech companies and academic institutes. In 2020 he became a co-founder and CEO of the Middle East Association for Pharmaceutical Professionals.

The Middle East Association of Pharmaceutical Medicine Professionals
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New offering of IFAPP's Continuous Professional Development Programme

INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

A free virtual training workshop on 01 and 02 March 2023 moderated by Dr Birka Lehmann and Dr Ingrid Klingmann

From 31 January 2023 all clinical trials with medicines must be authorised, handled and reported according to the rules lined out in the Regulation EU No 536/2014 (Clinical Trials Regulation).

The Regulation introduces an authorisation procedure based on a single submission via a single EU portal and data base, an assessment procedure leading to a single decision, rules on the protection of participants and informed consent, and transparency requirements. With this the Regulation will ensure a greater level of harmonisation of the rules for conducting clinical trials throughout the EU.

Therefore, all aspects of clinical trials are following new rules. This includes communication between sponsor, competent authorities and ethics committees. The new EU Database called CTIS (Clinical Trials Information System) is the key element. Sponsors will need to adapt their own systems and procedures to the new requirements in the European Union.

IFAPP offers you a free 2-day virtual training programme that will explain what you need to understand about the new processes, procedures and obligations of parties involved for updating your regulatory knowledge and for the preparation and conduct of your clinical trials in the EU. And the workshop will give you ample opportunities to ask your questions and discuss your concerns with experts in the fields.

Click **here** to register for the Training Workshop on **Wednesday 1 and Thursday 2 March 2023**.

Dr Birka Lehmann MD PhD is a Consultant in Pharmaceutical Medicine and a Board Member/Chair of the Education and Certification Working Group (ECWG) of IFAPP

Dr Ingrid Klingmann MD PhD is President of the PharmaTrain Federation and a member of IFAPP's ECWG

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INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

Audience: People from all around the world who want to understand the principles of the new EU regulatory environment for clinical trials, e.g., sponsors of clinical trials, clinical trial experts, investigators and site staff, regulatory affairs and medical affairs professionals, competent authority and ethics committee members, patient experts

Moderators: Ingrid Klingmann and Birka Lehmann
All session times according to CET

DAY 1 **01 March 2023**

10:00-10:10	Welcome and introduction
10:10-11:00	Clinical trial aspects that will change under the new EU Clinical Trials Regulation Q&A
11:00-11:45	The new "Single Dossier" in clinical development Q&A
11:45-12:00	**Break**
12:00-13:00	The Coordinated Clinical Trial Authorisation procedure: functioning, timelines and collaboration between competent authorities, ethics committees and the sponsor, also for substantial modifications Q&A
13:00-13:45	**Lunch**
13:45-14:45	The EU's clinical trial transparency rules from trial authorisation to result reporting – balanced between patients' needs for transparency and needs for protection of data confidentiality and commercially confidential information Q&A
14:45-15:05	**Break**
15:05-16:05	The Clinical Trials Information System "CTIS" – structure, functioning, requirements, training options Q&A

Moderated discussion: Advantages and hurdles of the new Regulation for sponsors of trials in different phases from within the EU and abroad
Open Forum Discussion with Moderators and Speakers

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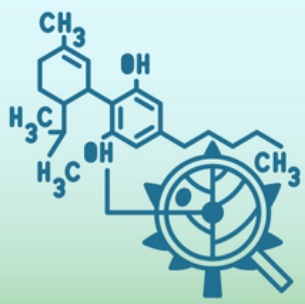
INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

DAY 2 **02 March 2023**

10:00-10:30	Getting access to CTIS within the EMA registration and filing systems Q&A
10:30-11:15	(Re?-)Organisation of responsibilities and oversight for sponsor and vendors required to achieve clinical trial authorisation in an auditable quality environment Q&A
11:15-11:35	**Break**
11:35-12:45	Reporting obligations during and after the clinical trial: study management, pharmacovigilance, technical summary and lay summary of trial results Q&A
12:45-13:45	**Lunch**
13:45-14:10	IMP Management under the Clinical Trials Regulation from definitions to labelling Q&A
14:10-15:00	Clinical trials in vulnerable populations under the Clinical Trials Regulation: minors, pregnant & breastfeeding women, emergency situations, incapacitated patients Q&A
15:00-15:15	**Break**
15:15-16:00	Challenges in the transition period between former Clinical Trials Directive and the new Clinical Trials Regulation Q&A
16:00-16:30	How should I prepare for the Clinical Trials Regulation in my work environment - All I could not ask before Open Forum Discussion with Moderators and Speakers
16:30	Conclusions and Farewell



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Innovative Options for Course Providers to Teach Medicines Development in New Formats and to More Stakeholders

In the 7 December 2022 IFAPP webinar, Dr. Kyoko Imamura gave an excellent overview of the challenges, and benefits of on-site and on-line courses addressed to different stakeholder groups.

The webinar shared in-depth information about the content of the course in Pharmaceutical Medicine to future experts and provided suggestions and opportunities by taking into account technical challenges and expanding the content of the course to other stakeholder groups like regulatory affairs, patients, children, and other interested parties.

The panelists Ingrid Klingmann (Belgium), Maria Caridad P. Purugganan (The Philippines) and Tatyana Benicheva (Bulgaria) questioned and contributed to the situation in relation to the very different stakeholders which were presented in relation to the experience with on-site and on-line courses and the challenges to create a course which is addressed to stakeholders of highly different background. The international audience, 35 participants from 15 countries/states, 15 of them IFAPP members, raised questions and suggested further formats to present Pharmaceutical Medicine to a broader audience.

Birka Lehmann, MD PhD GFMD, Chair IFAPP ECWG, Senior Expert Drug Regulatory Affairs

Good Lay Summary Practice - A New Standard for Communicating Clinical Trial Results

The year 2022 marked the start of a new era in clinical trials in Europe with the implementation of the EU Clinical Trials Regulation (CTR) and the Clinical Trials Information System (CTIS) going live on 31 January 2022. Significant new rules have come into effect alongside a series of non-legislative initiatives, bringing the hope of more efficient processes and greater patient benefit. Crucially, the new EU CTR has a focus on increasing transparency, notably in requiring trial sponsors to publish their results in lay summaries (LS), i.e., documents that are purpose-built to be accessible to everyone. Although some trial sponsors have been routinely producing reports aimed at non-professional audiences, this is the first time Europe has created a legal requirement and associated rules to inform patients and the public about each clinical trial in a manner which is easily understandable.

The new requirement for lay summaries is much more than a long-overdue courtesy to trial participants who obviously deserve clear information about how far their engagement has contributed to the advancement of science. It is also much more than an avenue for satisfying incidental curiosity about the development of a medicine or a treatment. What the systematic provision of these summaries amounts to is new and a necessary tool for developing and reinforcing the trust on which health research depends.

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Reliable and accessible information geared to a broad audience becomes a mechanism for dispelling public concerns that trials are part of an opaque black-box procedure. The impartiality implicit in these summaries offers the public and patients an unprecedented chance to understand what is going on in research, and gives researchers a channel to better communicate results.

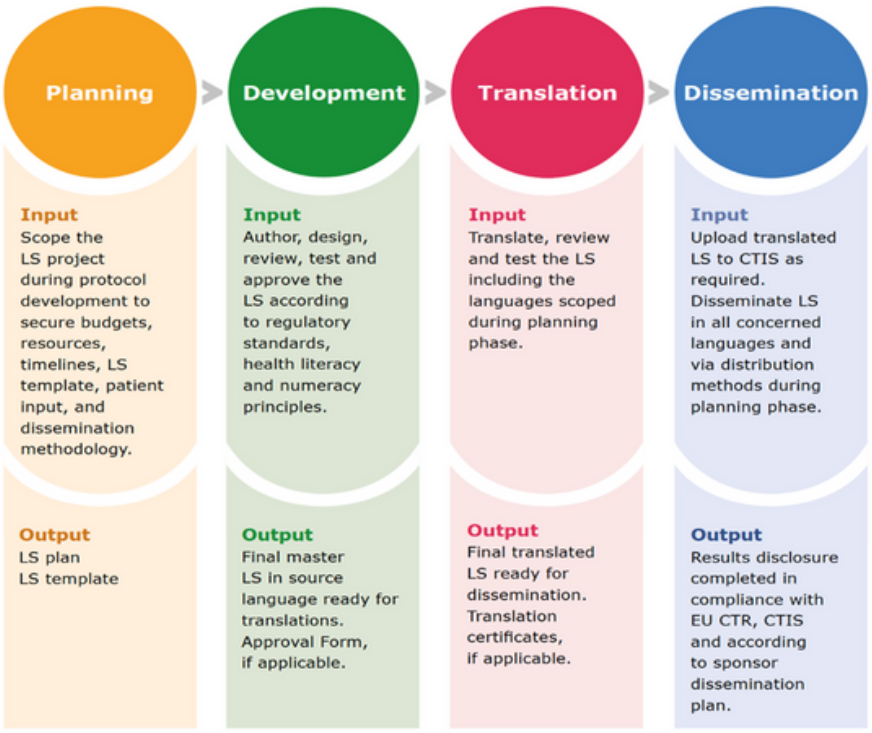
As The European Commission's Directorate General (DG) Santé conveys, supporting public confidence in clinical trial processes has a positive effect in the overall EU regulatory system for medicines. More systematic public disclosure of the aims and outcomes of individual trials is generating public confidence, contributing in turn to a more conducive environment for continued research.

While the concept of lay summaries is simple, its implementation is far less evident. The intrinsic challenges of combining readability and scientific rigour are undeniable, and the administrative aspects of planning, producing, translating, and efficiently disseminating these reports are complex and potentially onerous.

That is why over 60 participants from EU and US pharmaceutical companies, clinical research organisations (CROs), academic institutions, patient organisations and not-for-profit organisations formed the "Roadmap Initiative to Good Lay Summary Practice (GLSP)" under the joint leadership of EFGCP (1) and EFPIA (2). They created a draft guideline including a Quick Guide and Handbook with more specific guidance on meeting the new requirements. This draft guideline was reviewed by the European Commission's Clinical Trials Expert Group (CTEG), revised accordingly, and subsequently adopted by CTEG.

In a rare exception to EU rule-making procedures, it was published in late 2021 in EudraLex Volume 10 as the "Good Lay Summary Practice Guideline".

The content of the guideline reflects and builds on earlier work, both from the European Commission ("Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Version 2 (2017): Summaries of Clinical Trial Results for Laypersons") and the experience of sponsors in Europe and beyond (MRCT Center, TransCelerate Biopharma Inc.). One of the key elements is the recommendation to include patient engagement throughout the process of planning, development, translation, and dissemination of LS for adult and paediatric clinical studies.



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What stakeholders agree upon:

- A good lay summary is an ethical imperative and a good thing - for patients, for the public, and ultimately for regulation and for research.
- Producing a good lay summary is very demanding, and requires skills, time and resources, and a clear understanding of what GLSP really means in practical terms.
- Patient engagement will be critical throughout.
- There are still many unanswered questions about how the objective is to be fully and efficiently achieved.

This is why the Roadmap Initiative for Good Lay Summary Practice continues to jointly work on this topic:

- with a GLSP website providing access to up-to-date information on new developments and experience: https://glsp.network
- by raising awareness with workshops and webinars
- by offering training on GLSP for all stakeholders and on best options for collaboration.

Please join us in making this a global initiative!

Ingrid Klingmann, MD, PhD, President PharmaTrain Federation, Chairwoman EFGCP

(1) European Forum for Good Clinical Practice www.efgcp.eu
(2) European Federation of Pharmaceutical Industries and Associations www.efpia.eu

Highlights of the 2022 Swiss Annual Symposium in Pharmaceutical Medicine

The 27th Swiss Annual Symposium with the title **"Artificial Intelligence and Cutting-edge Therapies"** was again jointly organised by Dr Brigitte Franke-Bray and Dr Annette Mollet, both IFAPP Board Members, and held in the Music School Florhof in Zurich on 23rd November 2022.

The symposium was opened by a representative of IFAPP and by the president of SGPM. It consisted of three sessions in the morning and two sessions in the afternoon.

In Session I **Opportunities of Digital Health**, Dr Shibeshih Mitiku Belachew, Biogen, presented the latest developments in the use of digital biomarkers in Multiple Sclerosis, including improved MRI diagnostics to detect active lesions in the brain that are invisible to humans.

In Session II titled **Application and Impact of Artificial intelligence in Drug Development**, Dr Rippmann, Merck Darmstadt, talked about the use of machine learning models in drug development, e.g., to predict the toxicity of a molecule, or to enhance the design of a new molecule. In the second presentation, Dr Lukas Friedrich, Merck Darmstadt/MELLODDY Consortium, gave an overview of MELLODDY, a project that aims to enhance predictive machine learning models on decentralised data of 10 pharmaceutical companies without exposing proprietary information with the ultimate goal to increase efficiencies in drug discovery.

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Session III addressed **Ethical and Legal Considerations of Artificial Intelligence in Drug Development.** Dr Jeffrey Iqbal, University of Zurich, talked about the use of digital twins, e.g., in clinical trials, and how they could be used in the future. In the second presentation, Dr Agata Ferretti, ETH Zurich, highlighted the ethical and legal challenges of the digitalisation of health, with privacy issues being the most debated ethical concern.

Just before the lunch break, the **Wysch Body Music Duo** performed a surprise music set.

After lunch Session IV on **Advanced Therapeutics** followed, and this hot topic was addressed from many different perspectives. Dr Jens Grueger, Boston Consulting, highlighted the challenges of defining the value of new therapies and thus the challenges in negotiations with the payers and authorities. Dr Ansgar Hebborn, F. Hoffmann-La Roche, talked about these challenges and presented how joint health technology assessments are developed in Europe to overcome these problems. Furthermore, he gave an update on the EU HTA regulation which is currently under revision to improve the assessments. In the third presentation, Daniela Fazotta, University of Basel, explained the different aspects of "value", e.g., patient value and family/societal value which are often neglected in the overall assessment of new, innovative technologies.

The final Session V covered **Regulatory Aspects and Technical Aspects of Advanced Therapeutics**. In the first presentation, Dr Chris Williams, F. Hoffmann-La Roche, presented the current challenges in manufacturing and developing advanced therapeutics and how manufacturing costs could be reduced in the future. In the last talk, Dr Sebastian Schneider, F. Hoffmann-La Roche, addressed the current challenges in the complex supply chain from bench to bedside, and how they can be overcome in the future.

The SGPM President Dr Martin Traber, F. Hoffmann-la Roche, summarised all presentations before drinks and nibbles were offered to all attendees who were able to stay until the end. Following the analysis of the 2022 attendees' evaluations, the 2023 event will be planned.

One-hundred and nine professionals engaged in the development of medicinal products participated, and of these 61 were non-members of SwAPP (Swiss Association of Pharmaceutical Professionals) and SGPM (Swiss Society of Pharmaceutical Medicine), which was quite remarkable as, in the past, a majority of members from the two Swiss societies attended. Also, it was noted that quite a number of the participants were young professionals which was a first, and the organising committee was very proud to have attracted the younger generation. This was reflected by the two moderators, Dr Raoul-Dominique Giger, InnoMedica, for the morning session, and Dr Mathilde Ritter, Pfizer, for the afternoon session, who both chaired a meeting for the first time and they did an excellent job!

The symposium took place under the auspices of IFAPP, PharmaTrain, Scienceindustries Switzerland, vips (Association of Pharmaceutical Companies in Switzerland), SCTO (Swiss Clinical Trial Organisation), and Medical Tribune.

The event was sponsored by the Main Sponsor Roche and also by Alexion, CTC, Eli Lilly, GSK, Interpharma, Lundbeck, Novartis, Sanofi, SFL Services and Tigermed with CTC and SFL Services exhibiting their services.

SGPM/SwAPP awarded 6 credit points to the attendees of the conference.

Dr Brigitte Franke-Bray,
IFAPP Treasurer and Board Member
Dr Raoul-Dominique Giger,
SGPM Board Member

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Dr Annette Mollet, IFAPP Board Member and Chair of IFAPP's Young Professionals Working Group, presented an update on IFAPP at the beginning of the conference

Dr Raoul-Dominique Giger, the morning moderator

Dr Mathilde Ritter, the afternoon moderator

Dr Martin Traber, SGPM President opening the meeting

One of the breaks in the beautiful music hall

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30 Years GPMed (Austrian Society for Pharmaceutical Medicine)

Tuesday, December 13, 2022, 5 p.m.
Lecture hall of the Josephinum
Währinger Straße 25, 1090 Vienna

Figure 1: Josephinum, Vienna (1)

The 30-year anniversary of the Austrian Society for Pharmaceutical Medicine (GPMed-Gesellschaft für Pharmazeutische Medizin) was celebrated in the recently rebuilt lecture hall of the beautiful historical building Josephinum (Figure 1). The lecture hall, which we know from the engraving by Hieronymus Löschenkohl depicting the opening of the Academy with Giovanni Alessandro Brambilla's speech to the students of the Academy on November 7, 1785, is decorated with paintings of the great doctors of the early medicine, such as Galen, or Paracelsus. The Garrison Hospital was the military hospital located behind the Josephinum.

All attendees had the opportunity to visit the unique exhibition of wax models (Figure 2) that not only served as visual aids for trainee military doctors and surgeons but were also on display for the public - to teach them about the structure of the human body. In the spirit of the Enlightenment, Joseph II was committed to improving people's education. Therefore, the wax models were also accessible to the public. The entire exhibition reflects over 650 years of history of the institution and represents a worldwide unique treasure due to their abundance and diversity.

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Figure 2: Male full body model, 1785, representation of the vena cava system with heart (part of permanent exhibition Josephinum, Vienna, Austria).

Scientific programme:

"New European Approaches for the Future of Clinical Research", presented by Dr. Marianne Lunzer, Safety Assessor in the Clinical Trials Department of the Austrian Agency for Health, and Food Safety (AGES)

The new Clinical Trials Regulation of the European Union, which will come into force on January 31, aims to standardise and simplify the submission process for multinational, multicentre studies, according to Dr. Lunzer. Furthermore, the implementation of the new regulation should accelerate the clinical trial approval process and strengthen the European Union as a location for the implementation of large multicentre studies.

The basis for this is a new, electronic submission system called "Clinical Trials Information System (CTIS)", which replaces previous systems such as EudraCT submission. CTIS serves as a central hub for submission, safety reporting, changes to the protocol, study results and much more. Furthermore, all correspondence with the sponsor will be managed via this platform. The advantages of the new application system are shorter timelines and standardised submission documents, regardless of the country in which the study is to be conducted. The European Medicines Agency offers extensive training material to prepare for the new submission system, which can also be accessed on the AGES homepage.

"Data from patients for patients." Dr. Tanja Stamm, Centre for Medical Statistics, Informatics, and Intelligent Systems, Medical University of Vienna; LBI for Arthritis and Rehabilitation

In the second lecture of the evening, Professor Tanja Stamm from the Medical University of Vienna presented "Data from Patients for Patients", a lecture on ways to improve healthcare through targeted outcome research. Outcome research uses standardised real-world data for obtaining insights on treatment successes and outcomes, particularly from the patient's perspective. Dr. Stamm pointed out the lack of data existing on patient-reported outcomes of regular treatments, especially in Austria. This is to change, through an international project "H2O Health Outcomes Observatory" that is part of the Innovative Medicines Initiative (IMI) of the European Union and in which the Medical University of Vienna is participating as a consortium partner. The aim of this project is to establish independent facilities (observatories) in the participating countries Austria, Germany, the Netherlands, Spain, and Aarhus Hospital in Denmark as the latest to agree to collaborate with this project, which will conduct standardised, ethically, and legally robust collection of real-world data. Initially, this will be done for three disease areas (diabetes, cancer, inflammatory bowel disease). The goal of the initiative is to measure health outcomes more effectively to make more informed decisions.

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"Use of health data and digitalisation for the economy," Dr Alexander Biach, Deputy Director of the Vienna Chamber of Commerce

In the last presentation the importance of using health data and digitalisation in the commercialisation of the healthcare industry was discussed. Although the best-known use case of real-world data (RWD) has been in drug regulation, RWD are being generated and used by many other parties, including biopharmaceutical companies, payors, clinical researchers, providers, and patients, and can support incrementally the healthcare business. In this context, Dr. Biach presented the results of a new study commissioned by the Vienna Chamber of Commerce. The results of the study show that increased use of healthcare data in Austria would create an additional value of more than one hundred million Euros per year in the healthcare sector only. He also emphasises the importance of so-called digital health applications (DiGAs), also known as health apps. DiGAs are medical devices designed to aid in the detection, monitoring or treatment of diseases. While some DiGAs are already available on prescription in Germany where reimbursement processes have been established, this new technology is still not established among patients in Austria. Dr. Biach addressed the great potential for the future in the better use of health data, both for research, regulatory and commercial use but more important for better treatment of patients.

(1): The Josephinum is one of the most representative buildings dating back to Joseph II and is considered the most important example of classicist architecture in Vienna. Under Joseph II, the monarchy's medical institutions were expanded. His programme also included the upgrading of surgery with its own doctorate. Josephinum was established as an independent teaching institution with surgery as its main focus.

Assoc. Prof. Priv. Doz. Dr. Gerhard Garhöfer (Board member GPMed, Head of the Ophthalmopharmakologie, Universitätsklinik für Klinische Pharmakologie, Medizinische Universität Wien)
Priv. Doz. Dr. Ghazaleh Gouya-Lechner (Board member GPMed and IFAPP, chair of the IFAPP Communication Working Group, head of Gouya Insights).

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The Online Course will be held in the late afternoon of in total 8 days and additional self-study

Part 1 (2.5 ECTS)
I: Prereads
II: Introduction to drug Research & Development
III: Laws, guidelines & compliance
IV: Regulatory Affairs
V: Role profiles in Medical Affairs
VI: Project management & Medical Affairs plan
VII: Homework to create Medical Affairs plan
VIII: Individual assessment of Medical Affairs plan
Part 2 (2.5 ECTS)
IX: Drug safety & pharmacovigilance
X: Ethics, compliance & patient involvement
XI: Medical Affairs in healthcare system
XII: Presentation of Medical Affairs plan
XIII: Homework to further develop Medical Affairs plan
XIV: Individual assessment of Medical Affairs plan

Information on the course
This part-time blended learning program allows professionals to remain on their job and to integrate the training with professional activities. It is structured in 2 parts of blocked workshops. Workshops are offered online through engaging webinars.

Location
Online

Language
All courses are held in English

Duration
125 hours/5 ECTS

Certificate
Basic „Introduction to Medical Affairs and Pharmaceutical Medicine" certificate after successful completion of Part 1. Advanced certificate after completion of Part 2.

Tuition fee
Euro 1.600,- per part. Euro 3.200,- in total.
10 % discount for Medical University Alumni Club members and members of the GPMed („Gesellschaft für Pharmazeutische Medizin") at the time of application.

Start
Yearly

Application
clinical-research@meduniwien.ac.at

Learn about the specific role of Medical Affairs in the pharmaceutical industry

Apply now!

THE FLAG

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