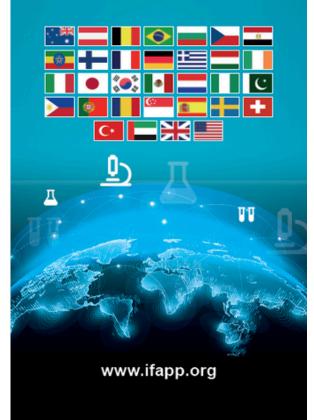


INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

IFAPP The only international organisation for everyone involved in Pharmaceutical Medicine



IFAPP TODAY

The Global Pharmaceutical Medicine Journal

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Congratulations to the 2024 IFAPP Fellows!

The announcement of the IFAPP Fellowship (IF) results is an exciting moment and it's important to share the process aspects.

The IFAPP Fellowship Committee allowed sufficient time to validate the applications and review the assessment results to ensure accuracy.

Twenty-six highly interesting and well-documented applications were received from Australia, Asia and Europe by the end of January 2024, which were thoroughly reviewed and accepted as valid by the end of February this year. In March, interviews with the 26 candidates were scheduled and conducted using a standard questionnaire and scoring system. Each candidate was interviewed by two members of the Fellowship Committee. The composite assessments of the candidates were finalised by the IF in May and ratified by the IFAPP Board.



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We are delighted to recognise and award them all in the following categories:

Rising Star Award in Pharmaceutical Medicine: 1 Fellow Award for Scientific Excellence in Pharmaceutical Medicine: 13 Fellows Award for Scientific Leadership in Pharmaceutical Medicine: 12 Fellows

The awards ceremony will take place at the next ICPM. Winners will be announced in "IFAPP TODAY" if they agree to have their names published.

A special page on the IFAPP website will be dedicated to the winners. It will be online and accessible after the ceremony, provided the winners agree to their names being published.

IFAPP will use appropriate channels to announce the overall results of the Fellowships and to promote next year's Fellowships.

By now all applicants should be aware of their awards.

Celebrating the achievements of the IFAPP Fellows should be a memorable moment of success for all the winners.

I would like to conclude this announcement by congratulating the 2024 IFAPP Fellows on this well-deserved honour, in whatever category they have won, and wishing them the very best in their careers.

We look forward to the continued growth of the IFAPP Fellows community.

On behalf of the IFAPP Board

Varvara (Barbara) Baroutsou IFAPP President

Join Us! Introduction of the IFAPP Ethics Working Group

Bioethical principles in Pharmaceutical Medicine, particularly in the development of medicines, are a very important issue. The aim of this Ethics Working Group (EWG) is to share and deepen the understanding of the wide range of ethical issues in Pharmaceutical Medicine, and to share current topics and their potential solutions. EWG's The activities are based on voluntary commitments, and members are free to participate on a voluntary basis.





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Currently, the EWG is working on the following topics on an ongoing basis:

- Recommendations for the revision of the World Medical Association's 'Declaration of Helsinki'
- Ethical issues in clinical trials in disaster settings
- Ensuring access to new investigational drugs and vaccines and benefit sharing
- Ethical principles and frameworks in Pharmaceutical Medicine

In addition, at the request of the EWG participants, the EWG also intends to consider the following issues facing Pharmaceutical Medicine today, such as:

- Ethical issues related to the use of Real-World Data
- Consent and governance issues related to data sharing and secondary use
- Shared decision-making
- · Diversity, equity and inclusive practice
- Ethical issues related to new technologies, considering vulnerability
- Patient, public, and community involvement activities

Anyone who is a member of a National Member Association or an individual affiliate of IFAPP can join this EWG.

We invite you to join us in a dialogue on the ethics of Pharmaceutical Medicine.

Administrative information:

Regular EWG meetings are held on the second Wednesday of each month from 13:00-14:00 CET Contact person and email: Kotone Matsuyama (Ms.), m-kotone@nms.ac.jp. Acknowledgement:

This text has been produced and reviewed by all EWG members as listed below. Thank you for your cooperation.

Anthony Chan (Ireland), Sandor Kerpel-Fronius (Hungary), Varvara Baroutsou (Greece), Sander Becker (Australia), Johanna Schenk (Germany), Shehla Naseem (Pakistan), Chieko Kurihara (Japan), Francis P. Crawley (Belgium), Eric Klaver (Netherlands), Yasmin Nagaty (Egypt)

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Kotone Matsuyama, GFMD, 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 the Ethics WG, IFAPP





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Clinical Pharmacology and Pharmaceutical Medicine in Belgium: The Making of a New Specialist Title for Physicians

Belgium has a vibrant health eco-system and combines worldclass patient care with a strong presence of pharmaceutical companies, resulting in a high number of clinical trials and a substantial contribution to drug development. Talent development is pivotal to further grow this eco-system and to attract future professionals. In Belgium there are two levels of specialisation for a Medical Doctor (MD) graduating from university after six years of training (level 1 title). According to the Royal Decree 25/11/1991, an MD can reach physician-specialist level 2 after four to six years of additional training (e.g., Internal Medicine). In addition, an MD can obtain a special competence, level 3 title, after two more years of training, only accessible for physicians with a level 2 title (e.g., Intensive Care Medicine).

Creating a new specialty starts with a proposal to the Minister of Social Affairs made by the High Council for Physician-Specialists and General Practitioners, which is organised by the Federal Public Service for Public Health. The High Council is composed of physician-representatives of all Belgian universities as well as of professional organisations and provides advice to the Minister who takes the final decision.

It is estimated that around 400-450 physicians are active in the field of the drug life cycle in Belgium (Janssens, 2018). Many of these professionals have an international career, so keeping the position of Belgium as a reference country in the field and further opening the European market by an international recognised specialty has an important added value.

The story

A first attempt to recognise Pharmaceutical Medicine and Clinical Pharmacology in Belgium goes back to 2008, where a dedicated working group of the High Council, with physicians who are members of the High Council, Academia (Clinical Pharmacology) and Industry (Pharmaceutical Medicine) were grouped together, under the leadership of the late Prof Jean-Marie Boeynaems. Both specialties have much in common as they both work on the drug life cycle, so it was reasonable to combine them into one specialty. The outcome of the discussions led to a recommendation for certification for both specialties, but without a follow-up.

In 2012 the first contacts were made with the chairman of the High Council at that time, followed by an attempt to complete a first template for Pharmaceutical Medicine in 2013. A dedicated group of four physicians, among them the authors of the article, working in industry and academia, persisted in aiming for a new recognition, and in 2015 the suggestion was made to create two titles: one for Pharmaceutical Medicine and one for Clinical Pharmacology with one approval. Although there were positive reactions, there was cold-water fear coming from different stakeholders to create additional specialist titles. A breakthrough was achieved when Patrick Waterbley, MD, vice-president of the High Council and coordinator for European questions, proposed to use the European Directive 2005/36/EG appendix V with the titles accepted within the EU, which require a minimum training of 4 years. As in this directive only "pharmacology" is mentioned, it was important to create a new title

including this terminology. This led to the proposal of the title of physician-specialist in Clinical Pharmacology / Pharmaceutical Medicine, confirming the training to acquire knowledge, skills and attitudes in the two complementary fields. Subsequently, the High Council created a new working group in 2017 with physicians representing the High Council, professors of Clinical Pharmacology of all Belgian universities, and physicians active in Pharmaceutical Medicine and clinical trials, under the leadership of Robert Lins and Patrick Waterbley.



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Based on the official template a proposal was made including motivation, situation, local and European context, requirements, accessibility and transitional measures. It was approved by the plenary session of the High Council in March 2019. Given the COVID-19 pandemic in 2020, there were other priorities for the Ministry of Health, and the publication of a Ministerial Decree was deferred. Under the new government, there was renewed interest, but in the meantime EU Directive 2018/958 on a proportionality test before adoption of new regulations on professions, was converted into Belgian law in 2021. Therefore, a public consultation of potential stakeholders was performed and a motivation for the proportionality was formulated, which was again approved by the High Council with an adapted version of the template in March 2022. Pharmacists were now included in the preparation of the new advice. The Ministerial Decree was published on 31 October 2023 in the Belgian Official Gazette (<u>CPPM</u>).

The law

In Europe, Belgium is, besides Switzerland, the UK and Ireland, the fourth country to recognize Pharmaceutical Medicine as a specialty for MDs and the eighteenth country to recognize Clinical Pharmacology (figure 1). The combination is until now unique and will allow the transition of professionals from the clinic to industry and vice versa. The new specialty is open for graduated physicians, with a basic diploma or a specialist title and requires four years of additional training. In case of another specialist title, part of that first training can be accepted for the new title. During these four years a theoretical training must be followed with a final examination, equal to other specialists. It contains a part common to all specialties for MDs and a part with specific courses, some mandatory, some elective specifically organised for the new discipline.

During the same period of four years, clinical internships (figure 2) must be performed for two years in departments with a great interest in the correct use of medications and medical devices, including Internal Medicine, Intensive Care, Paediatrics, etc. In addition, two more years of internship must be completed in the pharmaceutical and/or biotech industry, or in a regulatory environment.

Final competences are required in nine domains with a total of eighteen training modules. Transition measures are foreseen for those already active in the profession. The new recognition in Clinical Pharmacology / Pharmaceutical Medicine can be combined with other specialist titles.

Work not finished: The ongoing story

After the publication of the Ministerial Decree in 2023, the working group remains actively involved in the implementation of the new title. Procedures are created for the recognition of internships at the national level and for specialist-candidates at the level of the two regions (Flanders and Wallonia). The theoretical training programme is under development and can be incorporated by the universities in the overall training for specialists. This should result in a first official start of the new training in the academic year 2025-2026.

Conclusion

This specialist training in Clinical Pharmacology / Pharmaceutical Medicine for MDs will help to further professionalise the domain of drug development in Belgium. It will improve the quality and create a broader and more international perspective. Overall, it took almost 20 years to realise the new title. The main lesson learned was first to show perseverance. Secondly, providing clarity on the added value it would offer to all stakeholders at the governmental level, universities, professional physician organisations, industry and non-physician stakeholders was mandatory. Last, but not least, advocates at the level of each of these stakeholders will help to make steady progress.



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Janssens R, Present E & Casteels M. (2018) 'De mogelijke meerwaarde van een opleiding en bijhorende officiële erkenning voor Belgische farmaceutische artsen: een kwalitatief onderzoek'. <u>Tijdschr. voor Geneeskunde, 74(9) pp 595-604</u>.

Authors:



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*Healixia is the Belgian community of all professionals active along the life cycle of medicines, medical devices, invitro diagnostics and other health-related products. Members are active in research and development (including pre-clinical, early clinical and later phases), medical affairs, safety, regulatory affairs and market access in industry, academia, investigator sites, authorities, regulatory bodies or in consultancy. More information under www.healixia.be.

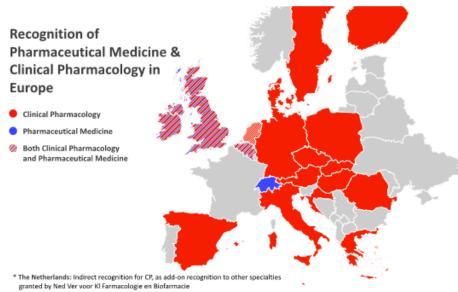


Figure 1: Recognition of Pharmaceutical Medicine and Clinical Pharmacology in Europe



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Training	Internships	Duration
Clinical	Internships in the hospital	2 years
Clinical Pharmacology / Pharmaceutical Medicine	Accredited internships in hospitals, industry, governmental organisations + specific places for training	2 years including minimum 1 year industry, min. 3 to max. 9 months in regulatory environment (FAMHP, RIZIV)

Figure 2: Internships for Clinical Pharmacology / Pharmaceutical Medicine FAMHP = Federal Agency for Medicine and Health Products; RIZIV = National Institute for Health and Disability Insurance

Artificial Intelligence in Medical Information in the Closing Act of the Second Edition of the Course 'University Expert in Medical Information in the Pharmaceutical Industry'

On March 20, 2024 the closing ceremony of the second edition of the 'University Expert in Medical Information in the Pharmaceutical Industry' course took place, organised by the Medical Information Working Group (AMIFE) and the CEU San Pablo University with the participation of twenty-four students. The event was chaired by the Vice-dean of Medicine at CEU San Pablo, Verónica Alonso, and by Pilar Ramos, Vice-dean of Organisation and Media, Teaching Staff and Research of the Faculty of Pharmacy, as well as by Mónica Rojo and Elena Molina, course directors and members of the Working Group.

Eduardo Tornos de Inza, a recognised expert in emerging technologies and digital skills in the field of health, was in charge of the closing conference. Under the title 'Artificial Intelligence in Medical-Scientific Information', the session marked the end point of the second edition of this course, the only postgraduate programme specialised in Medical Information that exists in Spain.



The course directors, Mónica Rojo and Elena Molina, with the students attending the closing ceremony.



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Eduardo Tornos went through the evolution of Artificial Intelligence (AI) in the health sector, highlighting that, despite the appearance of ChatGPT in the last 2 years, "we are getting on a train that has been circulating for 70 years, although it is only in the last 7 years that the changes have been seen". "The basis of everything are the data added Tornos - and there has been great dedication on the part of companies to collect these data (medical Apps, activity bracelets, etc.) to be able to achieve predictive medicine and transform the information into knowledge". The speaker gave a chronological presentation of the great milestones of AI in the field of health, stopping at some of the real practical cases of success that are already part of the daily life of medicine: among them, he highlighted the appearance of precision diagnostic tools or the first phase II drug discovered through Al. At the end of the conference, Eduardo Tornos posed a question to the audience: Do we need Albased systems to be perfect or simply better than humans??



Eduardo Tornos de Inza during his conference.

The importance of continuous training in the pharmaceutical industry

The Vice-dean of Medicine of the CEU San Pablo University, Verónica Alonso, highlighted in her intervention the concept of continuous training, field especially the professional of the in industry, "where, pharmaceutical in а multidisciplinary environment and in continuous innovation, it is necessary to know how to conveniently communicate all this information to the society." For her part, Mónica Rojo emphasised that "this course covers the lack of specific training in the field of medical information. Many professionals who work in the pharmaceutical industry need to expand their knowledge, although it is also an opportunity for people who wish to join this sector." The course consisted of 115 hours of class training and 24 students participated. She highlights that 80% of them are active professionals in the pharmaceutical industry, while the remaining 20% were students in the final years of the double degree in Biotechnology and Pharmacy at the CEU San Pablo University.

Author:

Anna Jurczynska, PhD, IFAPP General Secretary and Delegate of AMIFE



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Czech EUPATI National Platform Supports Patient Voice

The Czech EUPATI National Platform (ENP) was established in the summer of 2022 on the initiative of the first Czech EUPATI Fellow, Petra Adámková (Cohort 4), a patient advocate from ONKO Unie, an organisation supporting patients with gynaecological cancer. Together with Lenka Součková from Masaryk University in Brno and the research infrastructure CZECRIN, which is part of the European Clinical Research Infrastructure Network (ECRIN), and Lenka Břeská from Pfizer company in the Czech Republic, Petra initiated the establishment of the Czech EUPATI National Platform. Thanks to this collaboration, all three EUPATI pillars are represented in the Czech ENP: patient and academic sphere and pharmaceutical industry. Last year, the National Association of Patient Organisations joined the ENP and its leadership completed the original EUPATI Training in addition to the Czech course.





The Czech EUPATI National Platform was created with the aim to provide not only R&D education to patients in Czech, taking into account Czech conditions and legal environment, but also with the opportunity to study all the basic materials in Czech, participants are prepared for advanced/further study in English and EUPATI Fellow certification within the European training.

Over the last ten years, patient organisations have become a partner in the Czech Republic that are actively involved in decision-making and evaluation processes within the Czech healthcare system. The voice of patients is represented directly in the structure of the Ministry of Health by its own department and the Patients' Council, an advisory body to the Minister, patients participate in the HTA procedure for orphan drugs and are represented in important meetings of all stakeholders in the healthcare sector; not only in individual diagnoses but also in the whole healthcare system, including negotiations with payers and regulators.



The Czech EUPATI programme offers patients an introduction to the 6 core modules of the EUPATI training programme at face-to-face seminars and is provided free of charge to patients. Each module has its own guarantor and individual speakers from among university teachers, regulators, state administration and representatives of pharmaceutical companies. It covers knowledge on pharmaceutical development, clinical trials, drug safety, legal and ethical aspects, regulatory issues and HTA, including the very important localisation to the Czech environment so that the issues can be understood by patient advocates in the Czech Republic. In addition to these educational modules, EUPATI is also developing a Czech glossary of terms related to the subject matter. In the past year, 20 patient advocates completed the Czech training programme and are actively involved in the Czech Republic and Europe.



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EUPATI's education for Czech patients was made possible by its inclusion in the Academy of Patient Organisations (APO), an education and development project for patient organisations operating in the Czech Republic since 2012 across all diagnoses, and the support of the Association of Innovative Pharmaceutical Industries (AIFP).

Authors:

Petra Adámková, ONKO Unie,o.p.s., Lenka Součková, CZECRIN, Zuzana Komárková, APO, Lenka Břeská, Pfizer



From left: Petra Adámková (ONKO Unie), Lenka Břeská (Pfizer), Lenka Součková (CZECRIN), Zuzana Komárková (AIFP)



The first participants of the Czech EUPATI National Platform together with all speakers and guarantors, Prague 2024



From left: Jitka Kratinová (Muscular Dystrophy Association Czech Republic, the first Czech ENP "Fellow"), Petra Adámková (ONKO Unie), Lenka Součková (CZECRIN)



Picture from a Czech ENP seminar, Prague 2024



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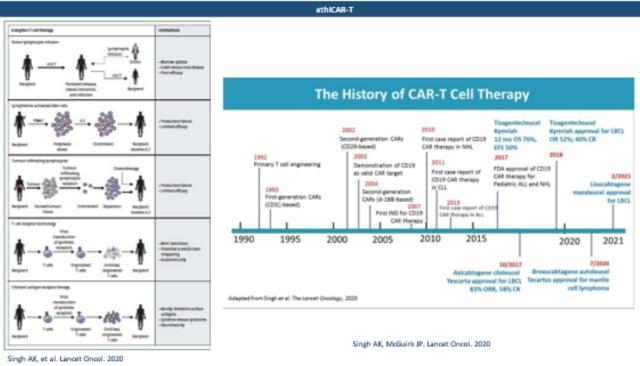
Report on IFAPP Webinar held on 29 May 2024: "CAR T-Cell Therapy and Ethical Aspects (Patients' Involvement)"

Speaker: Dr Antonio Pérez-Martinez, University Hospital La Paz, Spain

Panellists: Dr Yasuhiko Miyata (Miltenyi Biomedicines), Japan and Dr Ingrid Klingmann (EFGCP, Belgium)

The May webinar was brilliantly run by Dr Antonio Pérez-Martínez, Head of Paediatric Onco-haematology at University Hospital La Paz, Madrid. Trained in all the strategic health actions of the Health Institute Carlos III, he has become a reference in the treatment with natural killer cells (NK) in haematopoietic progenitors' transplantation and in advanced therapies (AT) with CAR T-cell therapies. He has optimised the procedure to manufacture clinical-grade NK cells for the use in the clinic. The Clinical Research Unit in Childhood Onco-haematology that he leads is accredited by ITCC.

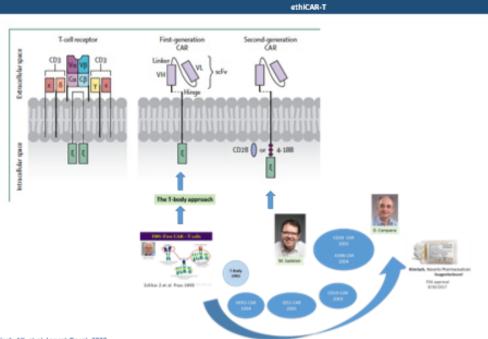
Ethics is an inherent and inseparable part of clinical medicine. The physician has an ethical obligation to benefit the patient, to avoid or minimise harm, and respect the values and preferences of the patient. Chimeric antigen receptor T-cell therapies (CAR T-cell therapies) have dramatically improved survival in CD19 and BCMA refractory/relapsed haematological malignancies. However, its potential is limited by several ethical considerations such as acute and delayed toxicities, access and equity, and financial implications. Minimising harm and maximise benefits to research participants in CAR T-cell clinical trials and to patients receiving approved CAR T-cell therapies is a key ethical obligation. Ensuring that CAR T-cell therapy is available to all patients who could benefit, regardless of socioeconomic status or geographic location, is also essential.





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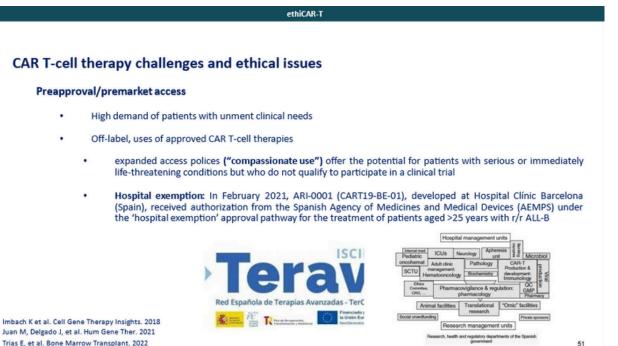




Singh AK, et al. Lancet Oncol. 2020

Sánchez-Guijo F, et al. Bone Marrow Transplant. 2023

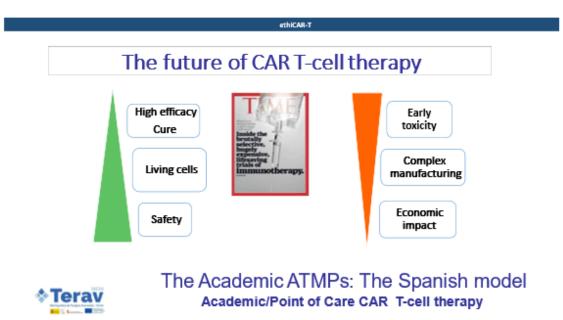
The high cost of CAR T-cell therapy raises questions about affordability and financial implications for patients and healthcare systems. Off-label and/or expanded access of CAR T-cell therapies under 'compassionate use' or hospital exemption pathway allow rapid access to them prepared on a non-routine basis, according to quality standards, offering an opportunity to patients with unmet clinical needs in close contact with clinical practice. However, off-label use should always be seen as an interim solution for the treatment of the patients in high unmet need and all necessary steps should be taken to change this into an in-label treatment. Some academic centres have developed point-of-care current good manufacturing practice CAR T-cell capability, improving patient access to CAR T-cell therapies and streamlining the costs of such therapies.





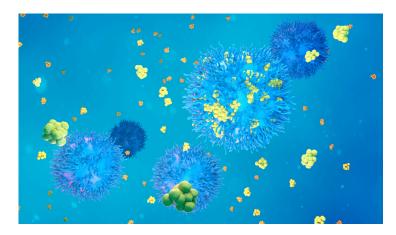
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The preliminary CAR T-cell programme was discussed at Hospital Universitario La Paz, Madrid, Spain, combining BioPharma and academic point-of-care manufacturing as a model to guarantee patients their ethical rights such as beneficence, nonmaleficence, and equity. The discussion was driven and centred by the topics mentioned above: interaction of all partners involved in CAR T-cell treatment (industry, physicians, patients) needed in the light of affordability of patients' unmet need treatment.

Author: Anna Jurczynska, PhD, General Secretary IFAPP Board and Delegate of AMIFE





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IFAPP TODAY

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IFAPP WEBINAR

Date: 27 June 2024



Time: 12:00 - 02:00 PM CEST

EU-CTR Update Workshop

Only 6 months left for transition!

Time Schedule 06:00 - 08:00 AM EST 10:00 - 12:00 AM GMT 12:00 - 02:00 PM CEST 07:00 - 09:00 PM JST



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IFAPP WEBINAR Date: 27 June 2024 Time: 12:00 - 02:00 PM CEST Pharmaceutical Medicine Moderator Speaker Speaker DR. INGRID OSKIA BUENO NICOLE WOIK KLINGMANN ZARAGUETA Experience with What has changed in Introduction to new working in CTIS, CTIS (since March developments in relevant changes 2023) from EMA's the CTR framework and requirements perspective? for the sponsor

The "Clinical Trials Regulation", Regulation EU 536/2014, has been valid since 31 January 2022 and mandatory since 31 January 2023. The "Transition Period" will end on 30 January 2025.

Practical experience of competent authorities and sponsors have detected deficiencies and gaps when applying for authorisation, authorising, supervising and reporting clinical trials in CTIS, the overarching Clinical Trials Information.

Register in advance for this webinar:

https://us02web.zoom.us/webinar/register/WN_U9r-DCsfQlu5EhfxfhViEA

After registering, you will receive a confirmation email containing information about joining the webinar.

Time Schedule

06:00 - 08:00 AM EST 10:00 - 12:00 AM GMT 12:00 - 02:00 PM CEST 07:00 - 09:00 PM JST



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MEAPP Conference Announcement

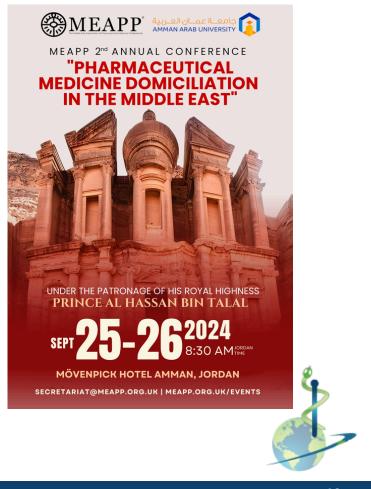
Under the patronage of His Royal Highness Prince El Hassan bin Talal of Jordan, MEAPP is holding its Second Annual Conference in Amman, Jordan on 25-26 September 2024 in collaboration with Amman Arab University. Building on its First Inaugural Conference in Cairo last year, this year's theme is "Pharmaceutical Medicine Domiciliation in the Middle East".

The rapid evolving field of Pharmaceutical Medicine is pivotal in shaping the future of equal and fair healthcare globally, and its development within the Middle East is of critical importance. Therefore, the planned conference seeks to raise awareness and foster understanding of Pharmaceutical Medicine as a recognized stand-alone specialty of multidisciplinary science in the region and serve as a catalyst for educational growth and innovation, aiming to draw the roadmap to enhancing the capacities of the region's next generation of scientists and professionals in this vital field.

The conference, occurring over the course of two days, will bring together an impressive roster of speakers from esteemed European institutions such as King's College London, the Faculty of Pharmaceutical Medicine (FPM) of the Royal Colleges of Physicians of the UK, and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). These experts, alongside delegates from regulatory bodies, the WHO Regional Office for the Eastern Mediterranean, and leaders from the pharmaceutical sector across the Middle East, will converge to engage in a vibrant exchange of ideas and insights.

Structured to maximize both learning and interaction, the preliminary agenda for the conference includes an array of keynote speeches, panel discussions, and workshops, as well as poster sessions for students and young researchers. Each segment is designed to address the most pressing challenges and the latest trends in clinical research, and new medicines development. These discussions will not only highlight current strategies and innovations but also explore the future directions of pharmaceutical medicine in the region and beyond.

Additionally, the event presents a unique opportunity for attendees to engage directly with global leaders and peers in the field of Pharmaceutical Medicine. Networking sessions are deliberately woven into the conference schedule to facilitate meaningful connections that extend beyond the event's duration. These interactions are intended not only to build professional networks but also to inspire scientific collaborations that could lead to breakthroughs in Pharmaceutical Medicine.



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THE FLAG

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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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