IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

GREEN Statement as the Result of Global Discussions Towards the Highest Ethical Standard of Research Ethics

Three consecutive meetings on Global Research Ethics were held by the **GREEN Statement** organisers, online on 25 August, hybrid on 13 September, and in person in Yokohama on 15 September 2025. The first of these meetings was reported in a previous edition of IFAPP TODAY (1) and the other two are detailed in this article. In connection to these activities the new book titled 'The 2024 Declaration of Helsinki: Global Efforts towards the Highest Ethical Standards', published by Springer on 17 September 2025 (2), was presented at a webinar on 29 September 2025, where the authors introduced each chapter.

As the remarkable outcome of these meetings, the 'GREEN Statement' (The Statement for **G**lobal **RE**search **E**thics **N**orms and Meaningful Engagement) (3) was issued. This Statement will be shared with international organisations involved in research ethics documents: The United Nations (UNESCO* and WHO*), CIOMS, and the WMA*. Until the end of October 2025, we

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welcome endorsements for publication in the journal, Clinical Evaluation Vol. 53, No. 2, after which the final version will be sent again to the above organisations. Details of the Statement can be found via this link.

We welcome your endorsement and contribution!

**United Nations Educational, Scientific and Cultural Organization; World Health Organization; Council for International Organizations of Medical Sciences; World Medical Association*

What is the GREEN Statement?

The Statement was developed based on the "Patient and Public Declaration of Research Ethics" (4), which was formed by a group of Japanese patients and the public, and it was discussed globally and intensively with participants in the three sequential meetings outlined above, reflecting the discussions in the aforementioned Springer book (2). The Statement promotes the protection of the rights of research participants and communities while it facilitates research that generates social value. A Global Research Ethics Norm should be developed through the equal participation of all interested parties. This norm should be based on already established fundamental human rights norms, while also simultaneously responding to the expectations and concerns of patients and the public regarding emerging cutting-edge technologies such as artificial intelligence (AI), genome editing, induced pluripotent stem (iPS) cells, and brain organoids, etc.

Rather than imposing regulatory limitations, we propose an expanded horizon of ethical principles considering the social and psychological impact of research on future generations and the ecosystem. The message of the GREEN Statement is to promote essential ethical norms while avoiding the bureaucratic procedural complexities and unnecessary burdens, and to provide consolidation for valuable research. Ultimately, this will contribute to global health, towards the achievement of Sustainable Development Goals (SDGs). We look forward to working together with the global research ethics community to achieve the GREEN Statement's goals. With this expectation, the Statement will be addressed to international organisations, such as UNESCO, WHO, CIOMS and WMA, to develop our Global Research Ethics Norm and Meaningful Engagement of patients, participants and the public.

Participants of the 13 September meeting: From the right to left: Masanori Okuse, Japanese Association for the Public Awareness of Psoriasis; the five authors of this article (VB, TS, DG, KM, CK); the four members of the Bioethics Working Group, of the Japanese Institute for Public Engagement (Ji4pe), Noriko Kishi, Toshie Murakami, Eiko Uchida, Keiko Inoue and Yoshiko Saito, and Prof. Ken Kato, Aichi Shukutoku University

At the 13 September hybrid meeting in Tokyo the GREEN Statement text was read and discussed line by line. At the beginning of this meeting, Prof. Hany Sleem, representing the Egyptian Network of Research Ethics Committees (ENREC) made an online presentation showing the Arabic translation of the GREEN Statement. The meeting was organised by the Brazilian Society of Bioethics and Ji4pe, supported by the Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM), IFAPP, and JAPhMed (Japanese National Member Association of IFAPP). Video Recordings of the 25 August and 13 September meetings are available (5)-(7).

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Speakers of the 15 September 2025 meeting: From the right, the five authors (CK, DG, VB, KM, TS) and Yoshiko Saito, leader of the Bioethics Working Group of Ji4pe.

On 15 September 2025, the second International Symposium of JAPERM, the terms “meaningful engagement” and “vulnerability” were discussed in depth. The session title was: “Transformation of the global research ethics: The 2024 revision of the Declaration of Helsinki to promote patient engagement and dynamic consideration on vulnerability”.

Acknowledgment:
The two of the three sequential meetings of 13 and 15 of September 2025 were funded by the National Center for Child Health and Development & Clinical Evaluation, in Japan.

References:

(1) Kurihara C, Matsuyama K, Baroutsou V. Global Research Ethics and Meaningful Engagement. IFAPP TODAY. 2025; No. 57: 4-6.

(2) Kurihara C, Greco D, Dhai A, editors. The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards. Singapore: Springer; 17 September 2025.

(3) GREEN. Statement Initiative. The Statement for Global Research Ethics Norm and Meaningful Engagement. Clinical Evaluation. 53(2).

(4) Patient Public Declaration of Research Ethics (1st edition): Research ethics of the people, by the people, for the people—Expanding the impact of the 2024 revision of the Declaration of Helsinki. Clin Eval. 2024; 52(3): W28-39.

(5) Video. Preliminary web conference. Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development. 25 August 2025, online.

(6) Video. Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development: Part 2. 13 September 2025, hybrid, Tokyo and online https://www.youtube.com/watch?v=D8k3Dh6kf80

(7) Consensus for Global Research Ethics and Meaningful Engagement (Leaflet for Three Sequential Meetings, Aug 25 online, Sept 13 hybrid and Sept 15 in Yokohama, in-person)

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Takeo Saio, Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital, Japan Dirceu Greco, Professor Emeritus of Infectious Diseases and Bioethics, Federal University of Minas Gerais, Brazil

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Bridging Japan and the Global Community: Highlights from the 16th Annual Meeting of the Japanese Association of Pharmaceutical Medicine (JAPhMed)

The 16th Annual Meeting of the Japanese Association of Pharmaceutical Medicine was held on 25 and 26 July 2025 in Nihonbashi, Tokyo. Approximately 200 participants attended, most of whom were members affiliated with pharmaceutical companies in Japan. The conference Chair was Dr Atsushi Kuga from Takeda Pharmaceutical Company Limited and a member of the board of the Japanese Association of Pharmaceutical Medicine.

The highlights of the two-day programme were as follows:

On the first morning, the Educational Session featured a lecture by Dr Hiroshi Nishiura of Kyoto University on 'Mathematical Epidemiology and Its Applications in Pharmaceutical Medicine: Current Status and Future Prospects.' In a separate session, Dr Sonoko Misawa, Professor of the Department of Neurology at Tokyo University of Science, discussed the collaboration between pharmaceutical companies and the utilisation of patient registry data.

In the afternoon of the first day, the Medical Safety Committee held an active discussion on the future of adverse drug reaction information provision. In another venue, topics related to the development of therapeutic apps were discussed. The highlight of the afternoon was the Conference Chair's special session, 'Considering Patient and Public Involvement,' which featured the powerful activities of Midori Senoo, Director of the Myotonic Dystrophy Patient Association; Ruby Kuroiwa, Representative of the Dravet Syndrome Patient Family Association; and Dr Hideo Miki (MD, PhD), of C4U Co., Ltd., who is working to develop new drugs in Japan.

The second day began with the second conference-chair led session, 'Frontiers in Development and Drug Discovery in New Modalities.' Three leading drug discovery researchers presented on new modalities, including nucleic acid therapeutics, mRNA (messenger RNA) vaccines, and cyclic peptides. Other sessions included a discussion on the revision of the MSL (Medical Science Liaison) certification standards by the Medical Affairs Committee, the importance of MSL education, and a session titled 'Challenges and Future Prospects for Drug Discovery Startups' by the Kansai Committee.

On the afternoon of the second day, Dr Tatsushi Toda delivered a lecture on the development of treatments for neurological disorders. Dr Toda, who has received numerous prestigious awards, including the Asahi Prize and the Bertz Prize, has an extensive body of work.

In the final Clinical Development Committee session on the second day, discussions focused on how to attract clinical trials and research in Japan, in line with the conference theme 'Creating the Future of Pharmaceutical Medicine Together.'

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In terms of collaboration with IFAPP, there were two notable events:

- During the reception on the first day, a celebration was held for the awarding of the IFAPP Fellowship. Four new Fellows had been elected, and commemorative gifts were handed over.
- Additionally, JAPhMed presented congratulations and commemorative gifts to Professor Kotone Matsuyama on her election as President-elect of IFAPP.

The final session on the second day was co-hosted by IFAPP and focused on 'Best practices in patient and community engagement.' The session overview was as follows: First of all, President Eric Klaver presented about IFAPP and then also talked about the scope of IFAPP activities: The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) is an international federation comprising Pharmaceutical Medicine societies from approximately 30 countries worldwide. The Japanese Association of Pharmaceutical Medicine is a national member association (NMA) of IFAPP. Within IFAPP, various working group activities are conducted to address challenges in the field of Pharmaceutical Medicine, promote international exchange, and advance initiatives such as Pharmaceutical Medicine education, ethics, communication, and the empowerment of young professionals. Additionally, IFAPP publishes a monthly newsletter, IFAPP TODAY, and hosts the International Conference on Pharmaceutical Medicine (ICPM), a biennial international conference.

In this final session, the focus lay on patient and public engagement as a key theme, inviting the IFAPP President and key opinion leaders to introduce relevant IFAPP working group activities and discuss best practices in patient and public engagement in Pharmaceutical Medicine.

The Programme Chairs were:

1. Dr Kyoko Imamura, Former IFAPP President; President, Japanese Institute for Public Engagement
2. Dr Kotone Matsuyama, President Elect, IFAPP; Director, Center for Clinical Research and Development, National Center for Child Health and Development

The Programme Sessions were:

1. Educational Programmes for Patient and Public Toward "Meaningful Engagement"
   Dr. Kaori Yukiyoshi, Specialist in Medicines Development, IFAPP/PharmaTrain
   Center for Innovative Clinical Medicine, Okayama University Hospital
2. The 2024 revision of the WMA Declaration of Helsinki and its impact on Pharmaceutical Medicine; Current status of public patient involvement and future perspectives
   Dr. Chieko Kurihara, IFAPP Delegate of JAPhMed, Specially-appointed Professor, Kanagawa Dental University; Editor-in-Chief, Clinical Evaluation, Member of Ethics Working Group, IFAPP
3. The Value of Patient Experience Data, Through Sustained Patient Engagement
   Mr. Nobutaka Yagi, President, YORIAILab Inc, Nippon Boehringer Ingelheim

The ICPM2027 is expected to be held in Japan in collaboration with JAPhMed. Unfortunately, this time, there was no session with national member associations from Asia, but we will continue to strengthen the collaboration with the Asian region in preparation for ICPM2027. We look forward to your continued support.

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Author: Kotone Matsuyama, President-elect, IFAPP

Congratulations to Professor Kotone Matsuyama for her election to IFAPP President-elect

The four IFAPP Fellowship awardees and the president of the JAPhMed annual congress (Dr. Atsushi Kuga)
Dr. Tsunehisa Yamamoto, Dr. Keiko Fukino and Dr. Ko Nakajo (each for the Rising Star, Early Career in Pharmaceutical Medicine)
Dr. Hidenori Komori (the Senior Fellowship Award)

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Collaboration for Global Justice and Humanity

Message of the new President of the Brazilian Society of Bioethics at the opening of the webinar of 29 September 2025 "The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards", covering the book with the same title published on 17 September 2025, to which IFAPP members contributed.

"It is a great joy to participate in the launch of this book (1), which crowns the efforts of a group of researchers from the Global South and Asia to develop Research Ethics as a field of knowledge that reflects the experiences of this part of the world, whose voice is often not heard. We are talking about populations with diverse characteristics and multiple layers of vulnerability, as Florencia Luna puts it. Or, if we prefer, we can speak of intersectionalities, in Kimberle Crenshaw's words, intersections of social disadvantages that exist for colonized, racialized, and impoverished populations.

However, if we want to consider humanity as an object of ethical concern, it means envisioning a world with justice, free from any form of oppression. Transforming the world to shelter humanity, living beings, and their environments, while upholding the goals of sustainable development, requires that science, especially clinical research, be conducted in every corner of the planet in true cooperation: both cooperation between researchers from different countries with highly unequal research infrastructures, and cooperation with research participants, whose voices need to be heard. This is not only about determining whether the intervention the participant is undergoing is effective and safe, but also about discussing the relevance of the design, the objectives, and how to use the results. This collaborative approach places human diversity and all its potential at the service of health for all.

It is a great honor for the Brazilian Society of Bioethics to participate in this project. I would like to congratulate the authors, and everyone involved".

(1) Kurihara C, Greco D, Dhai A, editors. The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards. Singapore: Springer; 17 September 2025.
https://link.springer.com/book/10.1007/978-981-96-9294-1

Author:
Marisa Palacios, MD, PhD
President, Brazilian Society of Bioethics

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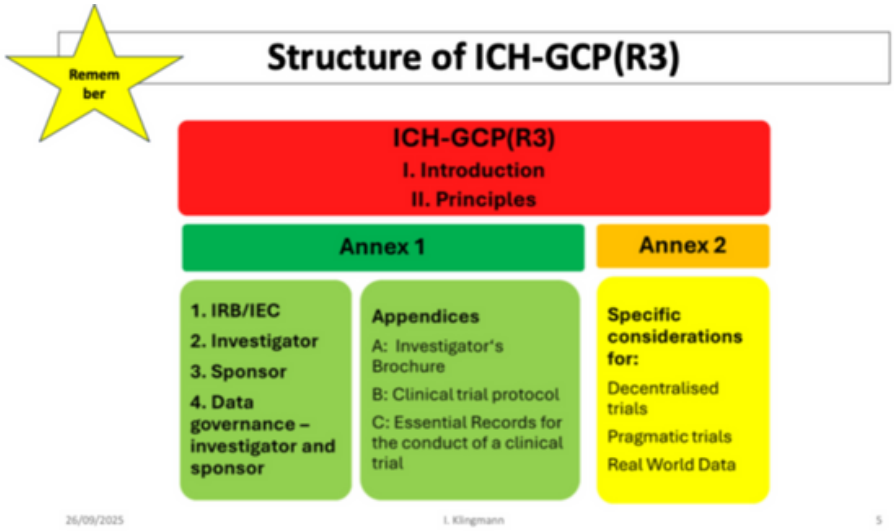
Summary of the virtual IFAPP Workshop of 18 September 2025: Practical Challenges of Implementing ICH-GCP(R3) in your Clinical Trials

Faculty:
Ingrid Klingmann, MD, PhD, PharmaTrain, Belgium
Eric Huber, MSc, Swiss Tropical and Public Health Institute, Switzerland

After a short introduction relating to the history of ICH-GCP revision 3, the new structure of guideline E6 revision 3 was presented.



The revision marks a significant rewrite of the guideline. A key feature is the use of two annexes to support the practical application of its 11 principles, promoting a risk-based, fit-for-purpose approach to trial conduct.

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In the four-hour expert inter-active training session, the attendees received a comprehensive update on the major revisions to ICH E6(R3) by discussing answers to questions like:

1. What do “Quality by design» and “Critical to quality factors“ mean in practice in your trial?
What has to be taken into account for sponsor obligations, trial design and processes and how to decide on what the Critical to Quality Factors (CQF) are in your trial?

2. How to assess and decide on “risks“ in your clinical trial and what does “risk-proportionate“ mean in practice? Risk Management – What Does It Mean in Practice?

3. How to decide on the required qualification and training needs? How to systematically define the competence a sponsor needs for a particular trial on the sponsor side and on the investigator side? How to deal with the gap between the needs for competent staff and the resources the sponsor and investigator have available in a particular trial? How to prepare a training plan for a specific trial?

4. How to enable reliable and seamless responsibility allocation and oversight between sponsor, service provider and investigator according to R3, also in decentralised trials?
What compromises ‘Responsibility Allocation and Oversight’?
For example:
Sponsor obligations for oversight request the definition of “important protocol deviations”. Is this the same as “serious breaches” in the EU Clinical Trial Regulation?

5. How to handle ethical aspects in relation to the Declaration of Helsinki and on eConsent?
But what to do when the Declaration of Helsinki, GCP and regulatory requirements are in conflict?
For example:
DoH: 23: When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host country.
ICH-GCP(R3): 3.8.2: Confirmation of Review by IRB/IEC
(a) Where reference is made to a submission to the IRB/IEC, this can be made by the investigator/institution or sponsor in accordance with applicable regulatory requirements.
EU Regulation 536/2014: Art.4: The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned.

6. How to apply the new Chapter 4 on data governance for sponsors and investigators?
For example:
Safeguard blinding in data governance and data life cycle elements.

- Metadata plays now an important role in R3. Who in the team should do the quality control of the metadata: the monitor or the data manager? How to decide on the metadata to be controlled – and to what extent? Is there a new topic for training of the monitor or data manager? This is an additional process from planning to archiving of metadata. Is this really necessary in every trial?

What about ‘Computerised systems’ Security? Validation? System release? Technical support? User management?

- Responsibilities of the sponsor, investigators and other parties with respect to computerised systems should be clearly defined.
- The responsible party should ensure that the system developer is aware of the intended purpose and applicable regulatory requirements for those systems.
- Involvement of representatives of the intended participant population and healthcare professionals should help to ensure that the computerised systems are suitable for their use.

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The overall conclusion was to be aware and adapt to the Principles of ICH-GCP (Rev 3):

Principle 1: Ethical Principles
Principle 2: Informed Consent
Principle 3: Ethical Review
Principle 4: Scientifically Sound Trials
Principle 5: Qualification of Staff
Principle 6: Built-in Quality
Principle 7: Risk Proportionality
Principle 8: Protocol
Principle 9: Reliable Results
Principle 10: Roles and Responsibilities
Principle 11: GMP for IPs

The full set of slides and the webinar itself can be found under the following links:

https://youtu.be/EwNy6_tVnaY
https://youtu.be/JhYNNNFGR0k

Authors: Ingrid Klingmann MD PhD, **Eric Huber** MSc, and **Birka Lehmann**, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

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Building Capacity for the Future: MEAPP Concludes the Final Module on Health Technology Assessment and Pharmacoeconomics

A milestone in the UK–Egypt partnership for advancing clinical research and evidence-based healthcare

Programme Overview

Last September, we proudly concluded the third and final module, **Health Technology Assessment (HTA) and Pharmacoeconomics, of the Capacity Building Programme for Enhancing Clinical Research and Drug Development in Egypt**, a collaborative initiative between King's College London (KCL), Future University in Egypt (FUE), and the Middle East Association of Pharmaceutical Medicine Professionals (MEAPP), funded by the British Council Going Global Partnerships Programme.

Hosted at Future University in Egypt (FUE) from 14–18 September 2025, the module brought together 38 participants from academia, governmental sectors, research institutes, contract research organisations, and hospitals for a rich week of applied learning and professional exchange.

Dr Laurent Pacheco at the Faculty of Pharmacy, Future University in Egypt, leading the HTA and Pharmacoeconomics Module

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Learning Journey

Over five intensive days, participants engaged in an integrated programme of lectures, workshops, and case studies, blending theory with hands-on exercises and real-world examples.
The module explored critical areas such as:

- Fundamentals of health economics and the typology of healthcare systems
- HTA dossier preparation and decision-making across agencies
- Budget impact analysis, pricing strategies, and pharmacoeconomic modeling
- Managed entry agreements and decision tree analysis
- The role of patient-reported outcomes (PROs) in cost-effectiveness assessments.

Each session encouraged dialogue, reflection, and the application of international best practices to the Egyptian context.

Instructors Dr Laurent Pacheco and Dr Assem el Baghdady, during a hands-on session on market access strategy development, highlighting the case study examples Futuremed and MEAPPmed.

Expert Contributions

The module was led by **Dr Laurent Pacheco, MD, PhD, MBA, FFPM, GFMD**, Visiting Senior Lecturer at King's College London, whose energy and commitment inspired participants throughout the week. His sessions combined conceptual clarity with practical examples, offering a comprehensive perspective on how HTA and pharmacoeconomics inform policy and market access decisions globally.

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We were honoured to host a distinguished lineup of guest speakers who joined us virtually to share their international expertise.

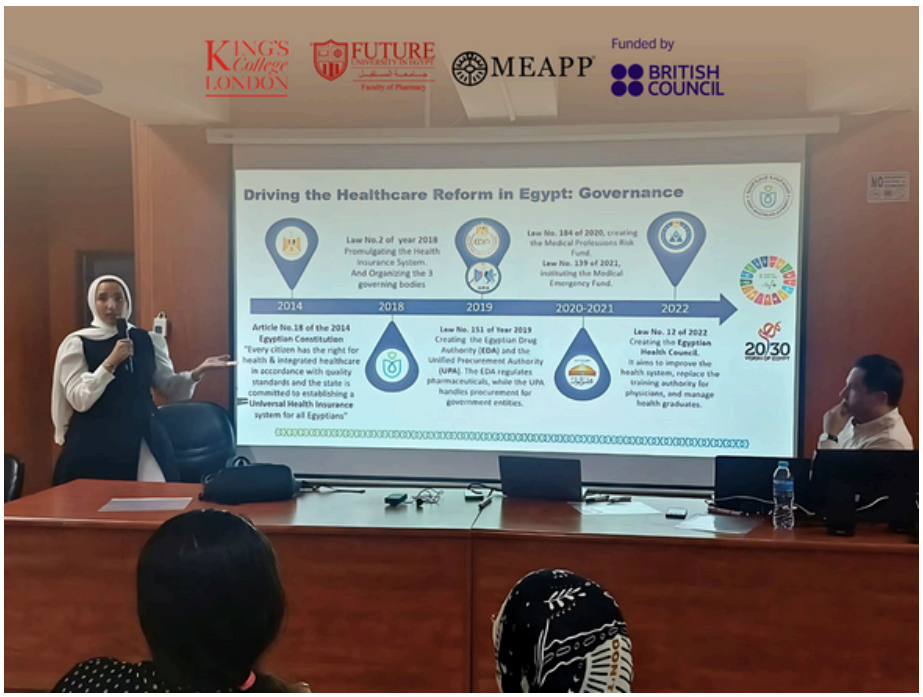
- **Prof. Manuel García-Goñi** – Professor of Applied Economics, Universidad Complutense de Madrid
- **Dr Sreeram Ramagopalan** – Senior Lecturer KCL/CEO Kairos Advisory
- **Dr Chris Teale** – Managing Director, TealeHealth Ltd, UK
- **Dr Gwilym Thompson** – Independent Health Economist

Their contributions enriched the discussions with real-world insights into HTA implementation, healthcare system evolution, and policy translation.

Closing Reflections

The module concluded with a career development and mentorship session led by Dr Pacheco and Dr Assem el Baghdady, Senior Lecturer at KCL and MEAPP President, encouraging participants to reflect on their career pathways in clinical research, HTA, and pharmacoeconomics.

A final discussion titled “Reflecting on the Egyptian Healthcare System”–featuring **Dr Nouran El Desouky**, Health Economics Unit Director, Egypt Healthcare Authority, who provided a forward-looking view of Egypt’s ongoing healthcare reforms and the growing role of HTA in supporting evidence-based decision-making.



Dr Nouran El Desouky presenting an overview of the ongoing healthcare reform in Egypt during the final day of the HTA and Pharmacoeconomics Module

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Looking Ahead

As this Capacity Building Programme concludes, it marks not an ending, but a foundation for continued growth. The collaboration between the UK and Egypt demonstrates the power of international partnership in strengthening research capacity, advancing evidence-based policy, and shaping the future of healthcare systems.

Looking ahead, embracing structured and transparent HTA is vital for the region to ensure that healthcare decisions remain evidence-based, equitable, and economically sustainable. Institutionalising HTA practices in Egypt and across the region will help optimise resource allocation, enhance patient access to innovation, and foster trust in health policy. Achieving this vision depends on ongoing training and capacity building, empowering professionals to apply HTA principles effectively and translate evidence into practice.

With this momentum, we look forward to seeing HTA evolve into a cornerstone of sustainable, patient-centred, and data-driven healthcare, contributing to both national progress and global dialogue.

Group photo of participants and facilitators in front of the FUE auditorium, marking the conclusion of the HTA and Pharmacoeconomics Module.

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Join us for an insightful webinar exploring the evolving professional identity within Pharmaceutical Medicine and medicines development.

Programme:

- 15.00 Welcome & Opening Remarks
  Dr Birka Lehmann, IFAPP
- 15.10 A collaborative effort to build professional identity in medicines development
  Dr Varvara Baroutsou, IFAPP
- 15.15 Panel discussion: The perspectives of Pharmaceutical Medicine organisations on professional development and the creation of a global community of experts
  Dr Ingrid Klingmann, PharmaTrain
  Dr Pravin Chopra, GMDP Academy
  Dr Sam Salek, GMDP Academy
  Dr Varvara Baroutsou, IFAPP
- 15.45 Q&A Session
- 16.00 Closing – **Dr Birka Lehmann**, IFAPP

Don't miss this opportunity to engage with experts shaping the future of Pharmaceutical Medicine.

Register in advance for this webinar

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

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Ethics in Data-driven Research:
WMA Declaration of Taipei on Health Databases and Biobanks
Part 2: Solidarity and morality of research participation: Asian experiences and perspectives

13 November 2025
CET: 11:00 to 12:00 am GMT: 10:00 to 11.00 am
JST: 19.00 to 20:00 Taiwan: 18:00 to 19:00
EST: 5:00 to 6:00 am

Registration to free webinar:
https://us02web.zoom.us/webinar/register/WN_7Ezs2hktTdWH9iSWusZSQg#/registration

The 2024 revision of the Declaration of Helsinki included the **Declaration of Taipei (DoT)** for the secondary use of data and biological materials obtained in research. This webinar will discuss about solidarity and morality of research participation in the era of data-driven policy making, sharing Asian experience.

Prof. Daniel Fu-Chang Tsai, National Taiwan University; Taiwan Medical Association, member of the Workgroup for the current revision of the DoT.

His talk will be based on this recent paper: Daniel Fu-Chang Tsai, Yu-Chen Juang. **The DoH, the DoT, and the Duty to Participate in Data Research: A Case Reflection from Taiwan.** In: The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards. Singapore: Springer; 17 September 2023.

WMA Declaration of Taipei (DoT)
https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

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21ST INTERNATIONAL CONFERENCE ON PHARMACEUTICAL MEDICINE 2025

Selected Accepted Abstracts from ICPM2025

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Title: **COST-EFFECTIVENESS OF DAPAGLIFLOZIN FOR HEART FAILURE: A RETROSPECTIVE-PROSPECTIVE ANALYSIS**

Author: Nehala Subeer, *PharmD intern at the National College of Pharmacy, Calicut, Kerala, India*

Summary: This study assesses the cost-effectiveness of combining dapagli6lozin with standard therapy (based on the GDMT guideline which includes: Beta blockers, ACE Inhibitors /Angiotensin receptor blockers/Sacubitril and valsartan/Spironolactone) versus standard therapy alone for heart failure. It was a six-month retrospective-prospective observational study involving 92 patients. Statistical analysis was performed to measure changes in ejection fraction (EF) and quality of life. The study aimed to determine if adding dapagli6lozin provides better clinical outcomes at a justifiable cost.

The results showed that adding dapagli6lozin to standard therapy is more cost-effective than standard therapy alone. While the combination therapy incurred higher costs for improving EF, it presented a positive Incremental Cost-Effectiveness Ratio (ICER), indicating that the additional expense correlates with enhanced health bene6its. Additionally, the therapy demonstrated cost savings when assessing quality of life through the Minnesota Living with Heart Failure Questionnaire (MLHFQ) score, with a negative ICER suggesting both economic advantages and improved patient well-being. Overall, the study found that dapagli6lozin, when added to standard therapy, yields better clinical and economic outcomes for heart failure patients. These 6indings emphasize the dual bene6it of dapagli6lozin in optimizing both patient quality of life and healthcare expenditure.

Why Considered: My proposal aligns with the ICPM 2025 theme, "Purpose for Future," by addressing the critical need for innovative and cost-effective therapeutic strategies in the management of heart failure, a growing global health concern. The study evaluates the cost-effectiveness of dapagli6lozin combined with standard therapy versus standard therapy alone, providing a forward-looking perspective on optimizing patient care and resource allocation in pharmaceutical medicine. Through a rigorous retrospective-prospective observational study, the research demonstrates that adding dapagli6lozin not only enhances clinical outcomes, such as ejection fraction, but also offers signi6icant cost savings and improved quality of life for patients. These 6indings contribute to a more sustainable future for healthcare, where effective treatments are accessible and affordable. By presenting this abstract, ICPM 2025 will showcase research that embodies the conference's purpose: to explore and promote future-oriented solutions that improve patient care while considering economic realities. This work will stimulate discussion on the evolving landscape of pharmaceutical treatments, fostering a shared vision for advancing the future of medicine.

What the Audience Gains: The audience will gain valuable insights into the costeffectiveness of dapagliflozin, when combined with standard therapy, in treating heart failure—a condition that presents significant clinical and economic challenges worldwide. They will learn about the latest evidence on how dapagliflozin can enhance patient outcomes, such as improving ejection fraction and quality of life, while also optimizing healthcare costs.

This presentation will provide a comprehensive overview of the study's methodology, including the innovative use of retrospective-prospective observational data, and a detailed cost-effectiveness analysis using both Average Cost-Effectiveness Ratio (ACER) and Incremental Cost-Effectiveness Ratio (ICER). Attendees will be equipped with practical knowledge on how to interpret these metrics and apply them in their own research or clinical practice.

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By the end of the presentation, participants will understand the dual impact of dapagliflozin on both clinical outcomes and economic considerations, which will help them make informed decisions regarding patient care strategies, resource allocation, and future research directions. The presentation will also encourage critical discussion on the broader implications of cost-effectiveness in pharmaceutical medicine, aligning with the conference's theme, "Purpose for Future."

Title: **IFAPP Pharmacovigilance Working Group**
Author: Lisa Stagi, *Patient Safety Country Cluster Lead EU Region at Roche, Italy*

Summary: In June 2024 it was established in IFAPP a new Pharmacovigilance Working Group (PVWG), marking a step toward enhancing patient safety and pharmacovigilance in pharmaceutical medicine: the group embodies a wealth of expertise and commitment, ready to tackle pharmacovigilance matters on a global scale. IFAPP underscores the importance of this initiative in fostering professional development through the knowledge and best practices exchange among its members. The group aims to address specialized pharmacovigilance requirements for novel therapies (e.g. cell and gene therapies) advocating for harmonization across regions and aims to provide guidance and support in the field of PV automation and new technologies like artificial intelligence application. Support in the evolution of PV legislation through the international platform provided by IFAPP is in scope of activities, as well as the collaboration with other IFAPP working groups and initiatives (e.g. with regard to PV education and training, acknowledging the need for solid qualifications to ensure high-quality work). Active participation from different countries will enrich our influence and knowledge in the international ecosystem.

Why Considered: to promote IFAPP activities in PV

What the Audience Gains: The possibility to contribute to IFAPP PV working group or to gain support through the working group activities

Title: **PV evolution and a survey from SIMEF working group**
Author: *Stefania Dellon, Affiliate Safety manager at Idorsia Pharmaceutical, Italy*

Summary: The higher level of systems automation associated with the digital transformation of pharmacovigilance (PV) daily activities showed that a deep change is occurring. The use of digital tools and artificial intelligence made it possible to streamline PV flows, automate some activities and improve quality and rapidity in completing routine tasks. Considering this changing environment and how to improve the culture and

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perception on PV to a more strategic function, the PV working group “Ernesto Montagna” of the Italian Society of Pharmaceutical Medicine (SIMeF ETS) create multidisciplinary events like conferences and scientific articles to achieve more fruitful collaboration and greater effectiveness in ensuring the patients well-being. A survey conducted by the group among PV specialists analyzed PV department role within companies and evaluated possible repositioning actions to enhance the scientific value of this function. Such survey highlighted how PV department is increasingly linked to the company’s internal and external functions. According to this, the group created initiatives involving partnerships with other scientific organizations demonstrating the ongoing changes and emphasizing the need for a comprehensive approach to PV activities. Future collaborations with healthcare professionals present opportunities to further improve patient safety, showcasing the dynamic and integrative nature of PV in contemporary healthcare.

Why Considered: This work described a new and comprehensive survey on the evolution of pharmacovigilance in pharma companies.

What the Audience Gains: new trends in pharmacovigilance and how pharmacovigilance can be more impactful through lifecyle of the products.

Title: **How the BEAMER B-COMPASS is improving patient support, outcomes, and cost-effectiveness of healthcare**
Author: Aad Liefveld, *member of the BEAMER project team and on the advisory board of Link2Trials*

Summary: Non-adherence to treatment has major impact to the efficiency and cost of healthcare systems and our wider societies. The BEAMER B-COMPASS is based on human behavior and provides a pragmatic framework designed to understand patient needs and create actionable sub-groups, enabling the future design and delivery of effective and targeted patient support. This approach enhances treatment adherence and persistence across all disease areas. The framework relates to all the HEOR top 10 focus areas, from health equity and patient centricity to value and pricing, providing a foundation for future development in precision medicine.

Why Considered: BEAMER is an EFPIA/IMI initiative to improve adherence. Human behavior is at the core of adherence to treatment, and BEAMER helps to provide better, personalized patient support in both clinical research and clinical care, thus resulting in more effective treatments and lowering healthcare costs and the economic impact of poor health.

What the Audience Gains: A better understanding of the behavioral aspects of adherence to treatment, the means to lower early drop-out rates and number of protocol deviations, the opportunity to deliver drugs and devices with an improved real-world performance, the potential to make healthcare more cost-effective and affordable.

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Title: **Analysis of Survey for HCPs for reporting ADR in Bulgaria**
Author: Niya Topalska, *Pharmacovigilance Specialist / Affiliate Safety Representative at Viatris Bulgaria*

Summary: The abstract details a survey conducted in Bulgaria to analyze adverse drug reaction (ADR) reporting by healthcare professionals (HCPs). The survey aimed to identify barriers and factors contributing to underreporting, assess reporting frequency, and understand the low reporting rate. The survey targeted 2849 medical specialists and was conducted using Microsoft Forms. The key findings of the survey include the fact that 55% of respondents never reported an ADR. Reasons for underreporting included ADRs being listed in the Summary of Product Characteristics (SmPC), lack of time, and uncertainty about reporting procedures. The survey highlighted three main areas for improvement: technology, education, and the overall reporting process. Recommendations to enhance ADR reporting and patient safety include integrating health information technologies, providing training, and standardizing reporting procedures.

Why Considered: The proposal should be considered as it offers a comprehensive analysis of the understanding of low ADR reporting, practical recommendations, and the potential to significantly improve ADR reporting and patient safety. The feedback garnered from medical professionals would not only be advantageous to the Drug Agencies but also hold value for other pharmaceutical companies. Such analysis could foster a constructive dialogue within the medical community, potentially enhancing pharmacovigilance practices and patient safety across the industry.

What the Audience Gains: Attendees will benefit from the quantitative data provided by the survey, which highlights specific issues that hinder effective ADR reporting. The presentation will offer practical recommendations for improving ADR reporting. Such analysis could foster a constructive dialogue within the medical community, potentially enhancing pharmacovigilance practices and patient safety across the industry.

Title: **30 years of ICH E7: do newly approved medicines in the EU cater to the needs of the geriatric patient population?**
Authors: Roisin Flynn, *Senior Director, ExploR&D at Eli Lilly and Company* & Niall O'Shea, *Quality Lead at Haleon, Ireland*

Summary: This analysis encompasses a review of the CHMP assessment report component of EPARs for medicines recommended for marketing authorisation in 2022 - as included in the EMA Human Medicines Highlights report - versus the recommendations of (a) ICH E7, (b) the EMA Geriatric Medicines Strategy and (c) the EMA Reflection paper on the pharmaceutical development of medicines for use in the older population. The list of medicines in the EMA Human Medicines Highlights report of 2022 was also compared to the list of novel drug approvals for the same period in the U.S.A. N=49 medicines were in-scope for analysis. It was notable that there were no medicines recommended for marketing authorisation for a cardiovascular indication.

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The greatest differences between the number of medicines recommended for marketing authorisation in 2022 by EMA, as compared to the FDA (CBER/CDER) were in the areas of Cancer, Dermatology, Diagnostic Agents and Haematology/ Haemostaseology.
83.3% of EPARs included a minimum of n=100 patients >65 years. 73.5% of EPARs (n=36) included patients >75 years. Of the analyses by therapeutic area, inclusion of n>100 of those >65 years was highest for Neurological and Endocrinology medicines and lowest for Nephrology and Haematology/Haemostaseology. A number of Haematology/Haemostaseology medicines were OMPs which limited the pool of geriatric trial participants. One Nephrology medicine restricted trial enrolment by having an upper age limit of 75 years, such cut-offs are specifically addressed in ICH E7.
A significant number of medicines were also excluded from traditional pharmacokinetics and drug-drug interaction studies by nature of their mode of action which limits the conclusions for these parameters.
Most EPARs appeared less closely aligned to the recommendations of the EMA Medicines Strategy and EMA reflection paper than those contained within ICH E7– particularly in the areas of off-label use, ease of administering the product through its container/ opening the container, stability in ADDs/MCAs/MDDs and excipients.

Why Considered: It has been widely established that older users of medicines have specific data generation needs in order that they may safely and appropriately use approved medicines. Historically, special populations (paediatric subjects, pregnant individuals and older persons – among other groups) were excluded from pre-marketing clinical trials which made age-appropriate and condition-appropriate prescribing decisions difficult.
There are now regulatory guidance(s) on how data in these populations is generated, e.g. ICH E7. However, studies have found differences between the population who participate in clinical trials and those prescribed the medicine in practice. Older adults also differ, in a regulatory sense, from the paediatric population in that there is no corresponding Geriatric Regulation to the Paediatric Regulation (Regulation EC 1901/2006). There is also no requirement for a Geriatric Investigation Plan, nor are there extensions to exclusivity provided as incentives.

What the Audience Gains: While EPARs are broadly aligned to the recommendations of ICH E7, 30 years since its implementation, a renewed focus by all stakeholders on recommendations contained within the EMA Geriatric Medicines Strategy and the EMA reflection paper on the pharmaceutical development of medicines for use in the older population would be beneficial to the older population.

Title: **The future of PAH Treatment**
Author: Nick Praet, *Clinical Research Physician at SGS, Belgium*

Summary: Introduction: Due to suboptimal current treatment, pulmonary arterial hypertension is considered a rare rare disease with an unmet medical need. The variation in etiologies leading to pulmonary hypertension makes it difficult to develop a one-size-fit-all treatment. In this review we looked into the current trials that are or were conducted with products indicated to be used in pulmonary hypertension patients.

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Method: A review has been performed on clinicaltrial.gov and the CTIS database to indicate which trials are described in patients with pulmonary hypertension and/or healthy volunteer trials for drugs intended for pulmonary hypertension.

Results: 815 trials were reviewed from which 422 were found to be investigational trials. 27,5% of the trials were performed with non-marketed IMP specifically for PAH, 10,7% with products marketed for other indications and 61,8% with drugs marketed for PAH. From the trials with non-marketed IMPs, 64,7% have stopped due to lacking endpoints or business decision. 23 products are still in development either in phase III, phase II or phase I.

Discussion: In the marketed drug for new indications and new IMPs, the shift from small molecule to biologics seems to be made. Different pathways are targeted, which can benefit patients with PAH with different etiologies.

Why Considered: In our proposal we describe the products in development for PAH, both new entities as already marketed product for other indications. In comparison to other publications, we do not look into the literature as these describe mostly the new discovered pathways or possible mode of action. In this presentation, we will give insights about products already in active clinical development and give insights about those that can shortly be expected to be used in clinics.

What the Audience Gains: Insights in the latest drug development for pulmonary arterial hypertension and the entities that might be close to market authorization.

Title: **The opportunities and current challenges in managing combined studies Drug/IVD/CDx/MD clinical studies**

Author: Vladimir Vujovic, Director, Clinical Trial Regulatory at IQVIA,

Summary: A successful drug trial protocol cannot be achieved without the use of various assays, which in Europe often fall under the definition of an In Vitro Diagnostic. The same applies to other Medical Devices. This session will explore the opportunities and challenges associated with the application procedures and execution of combined clinical trials in Europe. These trials involve a medicinal product alongside an in vitro diagnostic (IVD), companion diagnostic (CDx), and/or a medical device (MD) component. The clinical trial application for the medicinal product is submitted under the Clinical Trial Regulation (CTR) via the Clinical Trials Information System (CTIS). However, the application procedures for the device or diagnostic components follow different national regulations. The lack of an adequate regulatory interface presents unique challenges to research involving drugs and devices/diagnostics.

Key topics will include the harmonization of regulatory pathways, the integration of various components into a single trial, and the coordination required between different regulatory bodies. The session will also address the complexities of ensuring compliance with both the CTR and national procedures (under MDR/IVDR), highlighting potential obstacles and strategies to overcome them.

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An introduction and the latest updates, along with an industry perspective on the EC COMBINE project, will be provided.

Why Considered: The delay in clinical trials due to the lack of a regulatory interface for combined studies is projected to impact hundreds of studies. Multiple stakeholders are engaged in discussions to find solutions and mitigate the unintended negative consequences of the legislation, which is making the EU market less attractive for conducting clinical trials in fields requiring investigational diagnostic or device use (e.g., oncology, rare diseases, CNS, etc.). The European Commission's COMBINE project aims to streamline the process of conducting combined clinical trials by fostering collaboration between stakeholders and developing best practices. Introductions and the latest updates will be shared. Insights from the CRO perspective, representing sponsors of both drug, device, and diagnostic studies, will also be offered.

What the Audience Gains: Attendees will gain insights into the latest developments and practical solutions for navigating the regulatory landscape of combined clinical trials in Europe (trials involving the investigation of a medicinal product alongside either a medical device or an in vitro diagnostic device). They will also be able to describe the interface between different regulatory expectations for combined studies, understand and manage regulatory expectations for studies involving both a drug and a medical device/in vitro diagnostic, and demonstrate critical thinking and problem-solving skills in maintaining compliance within the EU regulatory context of combined clinical trials. Lastly, attendees will understand how the EU IVDR impacts the utilization of diagnostic devices for the purpose of clinical trial conduct.

Title: **Insights into the Comparative Safety and Patient Perspective on Subcutaneous Biological Drug Administration and Home-Care**
Author: Maaja Ivask, *patient safety lead at Roche, Estonia*

Summary: Subcutaneous (SC) drug administration is emerging as alternative to intravenous (IV) biologic therapies, as it can offer benefits like reduced hospital visits, improved quality of life, enhanced treatment adherence. To understand considerations that dictate safe and patient-centric strategies for SC administration, we conducted a series of complementary initiatives.
A first comprehensive literature review was conducted to consolidate existing knowledge on benefits of SC therapies for safety, patient preferences, and healthcare resource utilization. A parallel Italian project (ProSafe) focusing on patient preferences: a national survey created with patient associations and the University of Verona involving patients, caregivers, and clinicians. It highlighted positive attitudes toward digital applications that support home treatments. In Estonia a survey involving oncological patients revealed that receiving treatment in regional hospitals (vs local country hospitals) incurred significant costs. The majority of patients preferred closer-to-home care, which can be supported by SC treatments. This prompted a follow-up project with the Estonian Health Insurance Fund to create a cost-effectiveness model considering both direct and indirect healthcare costs to patients and society.

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These initiatives underscore the substantial benefits of SC administration from a patientcentric perspective, highlighting improved accessibility and overall positive reception while overall maintaining a comparable safety profile.

Why Considered: Insights on safety aspects of biological drug and innovative approach including patients' perspectives in safety.

What the Audience Gains: A deeper comprehension of the importance of considering safety aspects of subcutaneous biological drugs.

Title: **From complexity to clarity: Effective reporting of serious breaches in clinical trials**
Author: Angela King, *Director, Clinical Trial Regulatory Management at IQVIA*

Summary: Serious breach (SB) regulations have been common practice for many years in countries such as the UK and Spain with clearly set out expectations and requirements. EU CTR, Article 52 brings similar definition and requirements - a 'serious breach' means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial. EU Clinical Trial Regulation (CTR) brings onboard all countries within the region requiring additional surveillance of quality issues to determine serious breach status and timely reporting. Several countries in other regions have also followed suit with recent introduction of SB requirements within their local legislation and guidance. The pending ICH E6 R3 also includes similar suggestion for reporting of serious noncompliance which once released may influence further global uptake of such reporting requirements. The visibility and awareness on SB reporting is a hot topic within clinical research presenting an additional operational challenge to mitigate and ensure compliance with the strict timelines.
Perspectives from a large CRO and review of current publicly available data will be discussed to identify some key opportunities for preparedness, expectations of the regulators to de-risk noncompliance.

Why Considered: SB is a critical activity having the potential to impact any organization involved in clinical research. Adhering to the timelines and requirements is a challenge that is underestimated and this proposal will highlight those challenges and discuss ways to mitigate.

What the Audience Gains: Insights with regards to readiness activities to drive compliance, discuss case studies and associated challenges from available published SB in the EU Clinical Trial Information System (CTIS) and provide key recommendations on how de-risk noncompliance. Attendees will get a holistic picture of the specific SB challenges and proposed mitigations, gaining operational insights from the CRO perspective.

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Title: **Intellectual Property and Regulatory Incentives for Orphan Medicines: A Comparative Review of European and US Policies**
Author: Julian W. März, *Research Fellow at University of Zurich*

Summary: Rare diseases affect at least 300 million people worldwide, half of whom are children (Lancet Diabetes & Endocrinology, Spotlight on Rare Diseases, 2019). The US Orphan Drug Act of 1983 and the EU Regulation on Orphan Medicinal Products of 2000 were landmark initiatives aimed at fostering the development of treatments for rare diseases. Despite several hundred orphan medicine approvals in the US and EU over the past decades, more than 95% of the over 6,000 known rare diseases still lack approved treatment options.

This presentation will provide a detailed comparison of recent legislative and regulatory efforts to incentivize R&D for rare diseases in the US and EU. It will critically evaluate the strengths and limitations of these approaches and identify areas where current incentives fall short in addressing pressing policy needs.

Why Considered: Rare diseases represent a significant global health challenge, affecting over 300 million individuals, with more than 95% of known conditions lacking approved treatment options. This presentation provides valuable insights into how differing approaches in the US and EU shape the future of orphan drug innovation.

What the Audience Gains: Participants will gain a comprehensive understanding of current policies to incentivize orphan drug development in the US and EU, including how differing approaches shape innovation, access, and the future of orphan drug innovation.

Title: **Intellectual Property Strategy in Pharmaceutical Medicine**
Author: Takeshi Komatani, *Principle Patent Attorney and Adjunct Professor at TAKASHIMA International Patent Office & Kobe University*

Summary: The pharmaceutical industry operates at the intersection of innovation, regulation, and intellectual property (IP) protection. In recent years, rapid advancements in precision medicine, biopharmaceuticals, and orphan drug development have reshaped the strategic importance of IP in pharmaceutical R&D. This presentation explores the evolving role of intellectual property strategies in pharmaceutical medicine, in the data-driven drug development circumstances.

Key topics include the global IP landscape governing pharmaceutical patents, the life cycle management (LCM) of drug patents, and the integration of regulatory exclusivities such as data protection and market exclusivity with traditional patent rights. We will examine how IP strategies can maximize market access, extend product exclusivity, and mitigate competitive risks. The session will also discuss emerging trends in patenting methodologies, such as the role of medical affairs in knowledge creation, strategic patenting of drug formulations, new therapeutic uses, and treatment regimens.

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By analyzing case studies from leading jurisdictions—including the US, Europe, Japan, and China—this presentation provides practical insights into optimizing pharmaceutical IP strategies amid regulatory shifts and increasing competition. Attendees will gain a comprehensive understanding of how IP-driven approaches can be leveraged to enhance pharmaceutical innovation, navigate complex regulatory frameworks, and ensure commercial success in a highly dynamic industry.

Why Considered: The pharmaceutical industry is at a critical juncture where intellectual property (IP) strategy plays a pivotal role in sustaining innovation, ensuring market exclusivity, and navigating complex regulatory landscapes. This presentation provides a comprehensive, globally relevant, and forward-looking analysis of how pharmaceutical companies can optimize their IP strategies to maintain a competitive edge.

What the Audience Gains: The presentation "Intellectual Property Strategy in Pharmaceutical Medicine" offers a practical, globally relevant, and forward-looking discussion on how intellectual property (IP) can be leveraged to drive innovation, secure market exclusivity, and optimize pharmaceutical R&D investments. Attendees will leave with a deeper understanding of pharmaceutical IP strategies, enabling them to make informed decisions in an increasingly competitive and regulated environment.

Title: **Intravaginal delivery of oxybutynin via the MedRing OAB: a double blind three-way crossover study comparing intravaginal and oral oxybutynin administration**
Author: Bart van Rossum, *Chief Medical Officer at LiGalli*

Summary: Introduction:
The study explores intravaginal oxybutynin via the MedRing as an alternative to oral administration for treating overactive bladder (OAB). Oral oxybutynin is often discontinued due to anticholinergic side effects, notably dry mouth, linked to its metabolite, Ndesethyloxybutynin (DEOB). Intravaginal delivery aims to reduce these side effects by bypassing first-pass metabolism.

Methods:
A double-blind, placebo-controlled, three-way crossover study was conducted with 24 healthy females aged 18-45. Participants received 2.5 mg of intravaginal and 5 mg of oral oxybutynin. Various assessments, including cognitive tests and saliva production, were used to evaluate anticholinergic side effects and pharmacokinetics.

Results:
Intravaginal administration resulted in significantly shorter reaction times, higher saliva production, and fewer dry mouth complaints compared to oral administration. Stable plasma levels were maintained for up to 48 hours, with a 9.78-fold lower metabolite/parent ratio observed. However, the other neurocognitive tests, including the primary endpoint, showed no significant differences between intravaginal, oral administration, and placebo.

Conclusion:
Intravaginal oxybutynin was well tolerated and may serve as a favorable alternative for OAB treatment, potentially reducing common side effects that lead to treatment discontinuation.

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Why Considered: The LiGalli MedRing exemplifies a cutting-edge drug-device combination that leverages technological advances in medical devices to innovate drug delivery methods. Coupled with its app, the MedRing has the potential to offer a unique and effective personalized treatment option in women's health. Our study demonstrates its ability to reduce common side effects associated with oral medications, through an improved PKprofile, thereby potentially improving patient compliance, persistance and outcomes. By presenting this at the congress, we aim to engage in meaningful discussions on advancing women's health treatments and the future of drug delivery.

What the Audience Gains: Understanding Innovative Delivery Systems: Attendees will gain insights into the LiGalli MedRing as a novel drug-device combination that enhances drug delivery methods, showcasing the integration of technology in healthcare.

Clinical Evidence: The presentation will provide data from our study, demonstrating the MedRing's efficacy in reducing anticholinergic side effects compared to traditional oral oxybutynin, emphasizing its potential.

Impact on Women's Health: Participants will learn about the importance of advancing treatment options in women's health, particularly for conditions like overactive bladder, and how innovative solutions can address unmet needs.

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