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The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

Transforming Pharmacovigilance: Digital Innovation and Strategic Role in Modern Pharma

Summary

In recent years, Pharmacovigilance (PV) has faced challenges due to the need to adapt to rapid scientific advancements, the complexity of the pharma industry, and the digital revolution. Considering this constantly evolving scenario, the PV Working Group "Ernesto Montagna" of Società Italiana di Medicina Farmaceutica – Ente del Terzo Settore (SIMeF ETS), i.e. the Italian Society of Pharmaceutical Medicine – Third Sector Body, has supported projects aimed to promote the culture on PV matters among employees of pharma companies and to attract the interest of key stakeholders such as patients and healthcare professionals. Over the past four years, the group has worked on two articles to better understand the status of digital activities in

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pharma companies and the potential repositioning of the PV department. The group also published guidelines in 2022 to support PV departments in managing digital activities, addressing the lack of dedicated procedures and guidance from authorities. The latest survey conducted by the group in 2023 (with the associated publication carried out in 2024) highlighted a significant shift in the perception of the PV department within the companies and how digital activities and Artificial Intelligence (AI) are transforming its role from a bureaucratic and isolated department to an important strategic resource. This transformation involves increased collaboration with more and new departments and more intensive communication with patients and health care professionals. Based on this evidence, the PV Working group has focused its attention on promoting new skills and capabilities among PV specialists and supporting communication with patients and healthcare professionals, thereby enhancing the PV culture in the era of digital transformation.

Background

Since its inception in the 1960s, PV has undergone continuous evolution, progressing from a basic level mainly focused on the collection and analysis of cases in its earliest years to a complex system regulated by rigorous standards and laws with modern PV (1, 2). In recent years, PV has faced the challenge of adapting to rapid scientific advancements, the complexity of the pharma industry, and the digital revolution, maintaining the focus on patient safety. Considering this constantly evolving scenario, the PV Working Group "E. Montagna" of the SIMeF ETS has chosen to support projects aimed at promoting the culture of PV matters among employees of pharma companies and to attract the interest of final stakeholders like patients and healthcare professionals (HCPs).

Purpose

The interest in digital activities in PV increased after the COVID-19 pandemic experience of 2020, necessitating an increase in the use of digital media. The opportunities and challenges presented to HCPs/pharmaceutical companies by such scenario, suggested the need to better understand the role of PV in digital activities. In 2021, the group published the results of a survey revealing a broad consensus of the involvement of PV in digital channels, despite the early PV involvement in some companies (3). The lack of dedicated procedures and the absence of specific guidance from competent authorities have been highlighted as critical points. Following this evidence, the group published a guideline in 2022 (4) to support PV departments in pharma companies in managing digital activities, providing useful instructions on how to manage PV requirements in such scenario. These two projects, i.e. the survey and the guideline, highlighted the profound challenges in the PV activities linked to a relevant change in the perception of PV within the company. For this reason, in 2024, the group published an article on the evolution of the PV department in the pharmaceutical industry (5).

Discussion

The last project conducted by the group analysed the role of the PV department within the company to evaluate possible repositioning actions to enhance the scientific value of the function in the pharmaceutical corporate context. Two surveys among SIMeF ETS PV specialists and the Clinical Research & Medical Affairs/Real World Evidence (RICMA/RWE) groups were distributed in Italy in 2023 to analyse the perception of the PV department and the role attributed to it. The survey showed how the PV department was increasingly linked to the company's internal functions, granting it a more relevant strategic role. The departments of Regulatory Affairs and Quality, Medical Affairs and Marketing were classical functions interacting with PV; while a decreased interaction with some departments like Human Resources and Clinical Operations teams was highlighted. The higher level of systems automation associated with the digital transformation of daily PV activities showed that a deep change is occurring within companies. The use of digital tools and AI made it possible to streamline PV flows, automate some

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PV activities, and improve the quality and speed in completing routine PV tasks; this also led to embracing a paper-free approach to safeguarding the environment. PV transformation should be strictly connected to digital activities combined with the interactions of PV with other company functions. To facilitate the change of PV perception in the company, and the possibility of providing more strategic support in drug development and lifecycle via a more active and innovative role, a key element to consider in this scenario is the need to increase the knowledge of PV concepts and the awareness on PV activities at all levels, both within the company and among external stakeholders, including patients.

Conclusion

The evolution of the pharmaceutical industry is changing the perception and the positioning of the PV department within the companies: from a bureaucratic and isolated department to an important strategic resource, collaborating with more and new departments and communicating more intensively with the patients and HCPs. The digital media revolution and the attention to the patients and linked stakeholders are critical factors in the evolution of PV activities and PV processes, together, in parallel with the need to work according to the regulations and laws. SIMeF ETS has a key role in promoting new skills and capabilities among PV specialists and supporting communication with patients and HCPs. In recent years, this promotion has been also stimulated through scientific partnership and events with other national scientific associations such as Association of Pharmaceutical Industry Scientific Society (AFI), Italian Society of Pharmacology (SIF), Italian Society of Hospital Pharmacy and Pharmaceutical Services (SIFO), Italian Society, regulatory activities, access, pharmacovigilance (SIARV) and International Organization for Standardization (ISO) or SIMeF ETS working groups, such as RICMA, Italian Group Quality assurance in Research GIQAR and RWE to reflect the changes described above. These pillars have also been used as guidelines for the creation of events for 2025. Future cooperations with HCPs could provide further opportunities for reflection to improve PV awareness, as well as participation of SIMeF ETS representatives in the IFAPP PV working group.

1.Directive 2010/84/EU; Directive 2012/26/EU; Regulation 1235/2010; Regulation 520/2012; European Medicines Agency (EMA) Good Pharmacovigilance Practices (GVP)
2.Code of Federal Regulation (CFR) Title 21; Center for Drug Evaluation and Research (CDER) guidelines.
3.Lisa Stagi, Ilenia Bocchi, Salvatore Bianco, Grazia Sirizzotti, Daniela Bernardini, Valentina Calderazzo, Giacomo Pirisino, Ilaria Grisoni, Silvia Romano: “Pharmacovigilance and the digital world in Italy: presentation of the results of a national survey” Ther Adv Drug Saf 2021 Feb 10;12:2042098620985991;
4.Daniela Bernardini, Ilenia Bocchi, Stefano Bonato, Davide Bottalico, Valentina Calderazzo, Carmela Casino, Gian Nicola Castiglione, Carla Cottone, Stefania Dellon, Ilaria Grisoni, Amanda Mattavelli, Giacomo Pirisino, Silvia Romano, Grazia Sirizzotti, Lisa Stagi: ”Guideline proposal for pharma companies to manage pharmacovigilance activities in digital media” AboutOpen, 2022, 9: 21-28;
5.Lisa Stagi, Ilenia Bocchi, Daniela Bernardini, Marika Ciappa, Stefania Dellon, Gian Nicola Castiglione, Silvia Romano, Eros Fabrizi, Amanda Mattavelli, Ilaria Grisoni, Gabriella Finizia, Stefano Bonato: “The evolution of the Pharmacovigilance department in the pharmaceutical industry: results of an Italian national survey” Ther Adv Drug Saf 2024 Nov 4:15:20420986241293296.

Authors:

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Valentina Calderazzo, Local Patient Safety and Pharmacovigilance Lead, Boehringer Ingelheim Italia S.p.A., SIMeF Delegate

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Advancing Pharmaceutical Medicine in Egypt: A Transnational Education Initiative Led by MEAPP

The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP®), in collaboration with King's College London (KCL) and Future University in Egypt (FUE), has been awarded a prestigious Transnational Education Exploratory Grant from the British Council's Going Global Partnerships programme in November 2024.

The British Council's Going Global Partnerships programme supports collaborative initiatives between UK universities and overseas international higher education institutions, fostering stronger, more equitable, and internationally connected education systems. By supporting partnerships between universities, colleges, and other education stakeholders worldwide, the programme aims to enhance capability of higher education, science, and Technical and Vocational Education and Training (TVET) globally.

The project, **"A Capacity Building Programme for Enhancing Clinical Research and Medicine Development in Egypt,"** was selected for its potential to address the critical gaps in Egypt's healthcare sector. This initiative is designed to equip Egyptian scientists and healthcare professionals from various sectors with the necessary expertise and skills in medicine development, clinical research, and pharmaceutical innovation.

Spanning for one year and launched in January 2025, the programme kicked off with an inaugural event titled, "Shaping the Future: Leveraging Transnational Education and Capacity Building in Pharmaceutical Medicine in Egypt." This gathering brought together senior management, executives, dignitaries, and key decision-makers from the higher education, pharmaceutical industry, and clinical research sectors to learn and discuss the programme's strategic significance and its impact on the future of Pharmaceutical Medicine in Egypt and the Middle East region. Among the distinguished participants were the Secretary General of the Association of Arab Universities and former Minister of Higher Education, the Chairman of the Board of Directors of the Pharmaceutical Industry Chamber, and the President of the National Authority for Quality Assurance of Education and Accreditation, the Chairman and Secretary General of the Supreme Council for Clinical Research Ethics, Head of biological and innovative products and clinical trials at the Egyptian Drug Authority, and former Deputy Chairman of the Egyptian Drug Authority.

Notable speakers included Professor Ebada Sarhan, President of FUE, Dr Assem el Baghdady, Senior Lecturer at KCL and President of MEAPP, Mr Mark Howard, Director of the British Council in Cairo, alongside esteemed professors from KCL; Professor Stuart Jones, Director of the Centre for Pharmaceutical Medicine Research (CPMR), Professor Peter Stonier, Professor of Pharmaceutical Medicine, Professor Graham McClelland, Professorof Pharmaceutical Medicine, Professor Abdel Douiri- Professor of Medical Statistics and Clinical Trials and Dr Laurent Pacheco, Visiting Senior Lecturer.

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Mr Mark Howard, Director of the British Council in Egypt, addressing the audience. On stage: Prof. Ebada Sarhan, President of FUE, Prof. Hanan Refaat, Dean of the School of Pharmacy, FUE, and Dr Assem el Baghdady, Senior Lecturer at KCL and MEAPP President, with KCL professors joining online

The programme is structured into **three core modules**:

- Clinical Drug Development
- Drug Development Statistics and Data Management
- Health Technology Assessment and Pharmacoeconomics

Successful Completion of the First Module – A Major Milestone!

The Clinical Drug Development module, led by Dr Assem el Baghdady, MD, FFPM, FRCP, Senior Lecturer of Pharmaceutical Medicine, and President of MEAPP, marked the first significant milestone in the programme. This intensive five-day module (28 Jan– 2 Feb 2025) combined hybrid learning sessions and interactive workshops, bringing together 49 participants from diverse scientific backgrounds.

The module aimed to introduce the fundamental principles of clinical development strategies and key tools for planning and executing clinical development programmes. It explored the connections between regulatory processes, preclinical research, and early- to late-stage clinical development, providing a comprehensive understanding of core clinical development activities. Additionally, it covered the integration of real-world evidence in clinical research.

Participants were divided into groups, where each group was required to present a clinical development plan and target product profile as part of the assessment, in addition to completing the KCL multiple choice questions.

The outcome was outstanding, all participants successfully passed the assessment on their first attempt! Feedback was overwhelmingly positive, emphasizing the programme's value, impact, and contribution to Egypt's evolving pharmaceutical landscape.

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This prestigious collaboration between KCL, FUE and MEAPP® presents a unique opportunity to enhance the skills of professionals in medicine development, directly contributing to the advancement of clinical research and healthcare innovation in Egypt.

With the British Council's support, this initiative is poised to make a lasting impact on the pharmaceutical sector, paving the way for stronger research capabilities, enhanced patient outcomes, and greater industry growth.

Participants of Module 1 alongside Dr Assem el Baghdady and Prof. Hanan Refaat, Dean of the School of Pharmacy at FUE, capturing a memorable moment on the final day of the module

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EUPATI Norway: Strengthening Patient Involvement in Medical Research

EUPATI (European Patients' Academy on Therapeutic Innovation) is an organisation dedicated to promoting patient involvement by providing high-quality information and education. Our role is to train patients to make their voices heard transforming them into patient experts.

EUPATI Norway is one of 24 national platforms (ENPs) established across Europe and worldwide, promoting patient education and engagement at both national and local levels.

A Key Player in Patient Education

Established in 2016, EUPATI Norway represents the European Patients' Academy for Research and Development. The organisation consists of patients, research coordinators, and representatives from the pharmaceutical industry, working together to enhance patient involvement in medical progress.

We educate patients and caregivers and work to promote a network of Norwegian public and private healthcare stakeholders with the ambition of improving patient education and involvement in medical research and professional development. We offer education for users who wish to contribute to research and participate in patient panels as patient experts.

Vision and Goals

Vision: EUPATI Norway aims to educate patients and caregivers, enabling them to take an active role in medical development.

Goals:

- Increase patients' and caregivers' knowledge of medical research and access to medicines.
- Promote user involvement and partnerships with medical communities and the pharmaceutical industry.
- Train users to participate in advisory boards, committees, and ethical panels.
- Contribute to best practices for patient involvement in research, development, and evaluation of medicines.

Comprehensive Educational Programmes

EUPATI Norway does not provide disease-specific treatment information. Instead, it focuses on general principles of medical research and development. The training programmes developed or recruited by EUPATI Norway serve as a supplement to existing educational initiatives available to healthcare users. For disease-specific enquiries, patients are encouraged to consult healthcare professionals and patient organisations.

EUPATI offers various training platforms in English, including the extensive Patient Expert Training Programme. EUPATI Norway actively recruits users in Norway for this patient expert programme. The organisation also aims to develop its own educational curricula and training packages in Norwegian, based on EUPATI's established training programmes.

Expanding the Patient Expert Network

EUPATI Norway has a strong focus on increasing the number of Patient Experts in Norway. Over the past three years, we have supported several patients in completing this education, resulting in eight new patient experts, with four more set to graduate in 2025. By then, a total of 14 Norwegian members will have completed EUPATI's Patient Expert Programme.

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Our 4 patient expert graduates in 2024

To further this goal, we aim to raise awareness of this educational opportunity among Norwegian patient organisations and strengthen collaborations with patient organisations, academia, and industry. Expanding and increasing visibility is a challenging task, but we believe that the patient experts we support through education serve as excellent ambassadors for our work. serve as excellent ambassadors for our work. Our patient experts have contributed as representatives and patient voices in New Methods in Health Care, at seminars at NTNU (Norwegian University of Science and Technology), the research school of UiB (University in Bergen), in Norwegian and European projects and research and so on. So, we know that our patient experts are out there, using the education to the fullest.

Additionally, EUPATI Norway is working on organising seminars and webinars on topics relevant to our stakeholders, such as patient organisations, academia, and industry. Planned topics for this autumn include:
·Health Technology Assessment (HTA) for patients

- New Methods in Healthcare
- Clinical Trials

Each seminar will always begin with an introduction to EUPATI Norway, ensuring that all participants gain insight into our mission and activities.

Strengthening Nordic Collaboration

EUPATI Norway also maintains an ongoing dialogue with other Nordic national platforms, and we aim to further strengthen and formalise this collaboration in the coming years. Cross-border cooperation will enhance patient education efforts and facilitate knowledge-sharing across the region.

EUPATI's Global Reach

EUPATI has established National Platforms (ENPs) in 24 countries worldwide. These platforms work towards enhancing patient education and engagement at national and local levels, ensuring that patients have the necessary knowledge to contribute meaningfully to medical innovation.

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Commitment to Collaboration and Inclusion
EUPATI Norway is a patient-led organisation where individuals with chronic illnesses, disabilities, and their caregivers have significant influence. It is open to members nationwide, operates on an individual membership basis, and follows a democratic structure.

EUPATI Norway continues to work towards a future where informed and educated patients actively shape the development of new treatments and healthcare policies, reinforcing the importance of patient-centred research and collaboration.

Author:
Mona Sundnes, Deputy Chair EUPATI Norway

Level Up Your Career in Drug Development with ECPM's Certificate or Diploma in Pharmaceutical Medicine!

Are you a professional looking to deepen your expertise in drug development? The European Center of Pharmaceutical Medicine (ECPM) at the University of Basel in Switzerland offers a comprehensive postgraduate program designed to equip you with the knowledge and skills you need to thrive in the pharmaceutical industry.

The ECPM course offers two levels of qualification:
· **Certificate of Advanced Studies (CAS)**: Earn a CAS in Pharmaceutical Medicine by completing six modules and passing a multiple-choice examination.
· **Diploma of Advanced Studies (DAS)**: Elevate your credentials with a DAS in Pharmaceutical Medicine, which requires the multiple-choice exam, an oral exam, and an essay. (Note: The diploma also contributes to the Swiss Specialist title in Pharmaceutical Medicine for physicians.)

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What to Expect:

· **In-Depth Learning that Fits Alongside Your Work:** 24 days of face-to-face teaching, divided into six modules over two years.

· **Engaging Format:** A mix of lectures and case-oriented breakout sessions.

· **State-of-the-Art Insights**: The first three days of each module focus on fundamentals, while the fourth day is a seminar dedicated to new trends and developments in drug development science.

Module 1 of the 2025 – 2027 course cycle begins on **1st September 2025**. On behalf of Dr Annette Mollet, Professor Thomas Szucs, Monika Laskowski and Nicola Liversidge, we look forward to welcoming you!

Ready to join us for a journey of learning and new insights from molecule to marketplace?
Visit https://ecpm.unibas.ch/continuing-education/postgraduate-courses/certificate/diploma
Or Register at https://ecpm.unibas.ch/continuing-education/postgraduate-courses/diploma-course-1/cas-info-registration-and-final-exam

Don't miss this opportunity to enhance your career prospects in the exciting field of Pharmaceutical Medicine.

The ECPM Core-Team

Prof Thomas D. Szucs
Director

Dr Annette Mollet
Head of Education & Training

Monika Laskowski
Course Director

Nicola Liversidge
Course Coordinator

Please note:

Addendum to the first article in the March edition of IFAPP TODAY "IFAPP International Ethics Framework: a professional ethical guide for medicines developers" by Sandor Kerpel-Fronius, MD, PhD, DSc, FFPM, and Alexander L Becker MB. BCh, FFPM, GFMD, Dip Business Management: The literature reference was not complete, so here it is: Kerpel-Fronius S. and Becker AL. "The Value and Importance of a Professional Ethical Code for Medicines Development: IFAPP International Ethics Framework. Pharmaceutical Medicine. 2025. https://doi.org/10.1007/s40290-024-00547-6

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Announcement for Second Digital Health Africa Conference 3-4 September 2025

The first-ever Digital Health Africa Conference (DHA-2024) successfully showcased progress in digital health, telemedicine, precision medicine, real-world evidence, pharmacometrics and artificial intelligence and how these can advance healthcare delivery across Africa (https://digitalhealthafrica.org/).

Building on this success, we are delighted to announce the Second Digital Health Africa Conference, DHA-2025 on 3-4 September 2025. This will use an innovative conference design to enable networking in a sustainable manner, with physical venues in Berlin, Pretoria and Kampala virtually networked together. DHA-2025 will provide further practical insights into the potential applications of digital technologies, using maternal and neonatal health, a major unique challenges of medicine in Africa. Topics of interest will include patient registries, safety signals of special interest, vaccine use in pregnancy/breastfeeding, labelling of vaccines in pregnancy, emerging infections and antibiotic resistance, telemedicine, pharmacometric modelling, precision medicine, medicines regulation, ethical and legal aspects, and capability enhancement.

Our target audience includes Experts in digital health and related fields from industry, academia, funders/payers, and regulatory agencies; Experts in maternal and neonatal health; Pharmacometrics specialists; Medical practitioners and other health professionals; Healthcare providers and payors/funders; Industry, including digital start-up companies; Non-profit organisations; Government officials; Patient representatives; Postgraduate students.

Registration opens in April 2025.

Author:
Professor Catriona Waitt
Professor of Clinical Pharmacology and Global Health
University of Liverpool/ Infectious Diseases Institute, Makerere University

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Ethics in Data-driven Research: WMA Declaration of Taipei on Health Databases and Biobanks

Free Webinar

Part 1: Introduction and future direction

06 May 2025

CEST: 12:00 noon - 1:30 pm, JST: 8:00 - 9:30 pm

EST: 7.00 to 8.30 am

Click here or copy to register:

https://us02web.zoom.us/webinar/register/WN_Zla4nW7aR6me_-iwLozXuw

The 2024 revision of the Declaration of Helsinki included for the first time the **Declaration of Taipei (DoT)** for secondary use of data and biological materials obtained in research. This webinar will introduce the background and contents of the DoT and discuss future directions.

Dr. Jon Snaedal
Icelandic Medical Association
Chair of Working Group for 2016 Declaration of Taipei

Dr. Miguel R. Jorge
70th President (2019 to 2020) World Medical Association

Dr. Otmar Kloiber
Secretary General
World Medical Association

WMA Declaration of Taipei

https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2020.579714/full

Infographics

http://cont.o.oo7.jp/50_1/IFAPPToday-DoHDoT-Poster-English.pdf

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Summary of the Webinar of 20 March 2025: Cardiovascular Sex and Gender Pharmacology

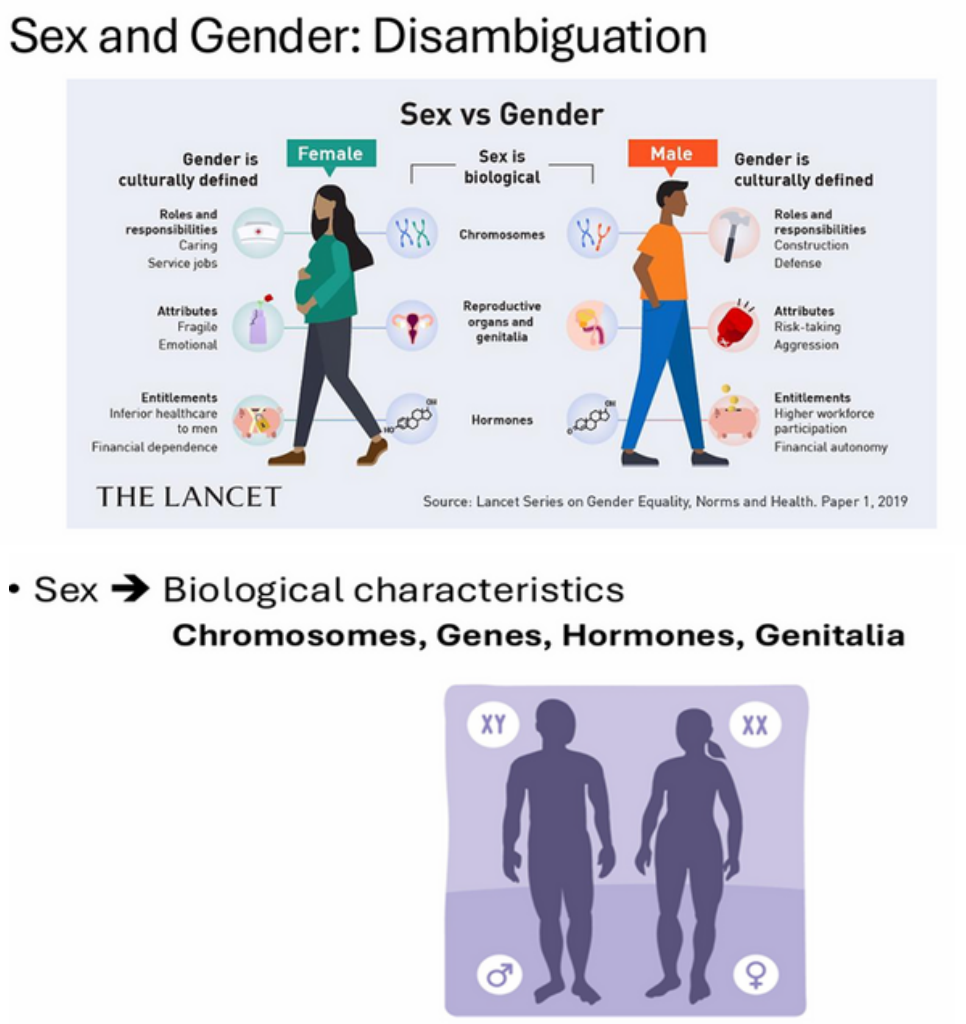
The speaker was **Dr Rubén Fuentes Artiles**, a medical doctor with a specialisation in Sex and Gender-specific Medicine (Certificate of Advanced Studies from the Universities of Zurich and Bern, Switzerland). He started his education as a cardiologist at the Limmattal Hospital and the Triemli Hospital in Zurich and is currently working as a Resident Physician at Bern University Hospital (Inselspital) in the Department of Cardiology.

Overview

The webinar focused on exploration of sex differences in cardiovascular pharmacology by examining specific examples of commonly used cardiovascular drugs like ACE inhibitors.

Following the presentation, an open discussion session took place and provided an opportunity to collectively draw conclusions and explore future directions in cardiovascular pharmacology

Why is there a need to focus (more) on gender differences?



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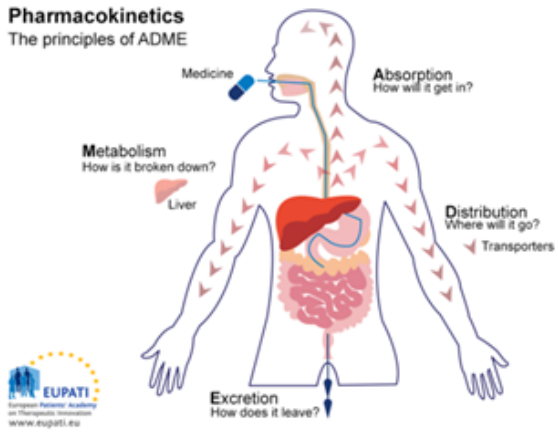
Sex differences in pharmacokinetics

Pharmacokinetics



Absorption

- Gastric secretion and emptying central process => Secretion higher in women, emptying time shorter in women
- Intramuscular absorption slower in women
- Transdermal unclear => more sc adipose tissue in women, larger skin pores
- Pulmonary unclear

Soldin OP, Chung SH, and Mattison DR (2011) Sex differences in drug disposition. J Biomed Biotechnol 2011:187103.

Distribution

- Women smaller, lower total body volume, lower extra- and intracellular and total blood volume, fewer red blood cells, lower cardiac output, lower organ bloodflow rate

➔ all contribute to volume of distribution (Vd)!

- Plasma protein binding influenced by endogenous and exogenous estrogens (e.g. lidocaine)
- Different body composition

Fadiran EO and Zhang L (2015) Effects of sex differences in the pharmacokinetics of drugs and their impact on the safety of medicines in women, in Medicines for Women (Harrison-Woolrych M ed) pp 41–68, ADIS, Geneva

Metabolism

- Liver main site of drug metabolization
- Dependent on bloow flow, cardiac output (therefore sex and pregnancy)
- Activity of enzymes dependent on several endogenous and exogenous factors
- CAVE botanicals!

Smirnova OV (2012) Gender-related differences in drug effects: the role of multidrug resistance proteins. Hum Physiol 38:331–341.

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Elimination
• Tubular secretion, reabsorption, GFR ➔ all lower in women
• Slower clearance of active metabolites in women compared with men (e.g. pregabalin, vancomycin, some anticoagulants, etc.)
• Avoidance of adverse effects is central

Anderson GD (2005) Sex and racial differences in pharmacological response: where is the evidence? Pharmacogenetics, pharmacokinetics, and pharmacodynamics. J Womens Health (Larchmt) 14:19–29.

Gut Microbiome
• Bioavailability usually less than 100% and often less than 60%
➔ exposure of gut microbiome to drugs
• Efficacy of medication likely to be enhanced or worsened by modulation through microbiome

Bernbom N, Nørrung B, Saadbye P, Mølbak L, Vogensen FK, and Licht TR (2006) Comparison of methods and animal models commonly used for investigation of fecal microbiota: effects of time, host and gender. J Microbiol Methods 66:87–95

Sex-specific cardiovascular pharmacology – what we already know!

Digoxin
• ➔ Digoxin should be titrated more carefully in women and serum levels monitored closely (also in men) to avoid adverse effects (narrow therapeutic index)

Beta blockers
• Cornerstone of heart failure treatment
• Metoprolol and propranolol metabolized by CYP2D6 ➔ lower activity in women compared with men
• Propranolol levels up to 80% higher in women
• 50 mg of Metoprolol in women = drug exposure to 100 mg in men
• ➔ Women with heart failure might require lower doses of beta blockers than men for optimal effects.

ACE inhibitors
• Used for blood pressure treatment as well as heart failure management

• Women with HFrEF reach same treatment effects with lower doses and do not benefit from uptitrating to guideline- recommended doses
• Adverse effects (e.g. dry cough) more frequent in women
• ➔ Women might require lower doses for optimal effects.

Mackay FJ, Pearce GL, and Mann RD (1999) Cough and angiotensin II receptor antagonists: cause or confounding? Br J Clin Pharmacol 47:111–114.
Santema BT, et al.; ASIAN-HF investigators (2019) Identifying optimal doses of heart failure medications in men compared with women: a prospective, observational, cohort study. Lancet 394:1254–1263.

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Aldosterone receptor antagonists

- Trends towards greater benefit and reduced mortality in heart failure for women
- So far lack of prospective studies and RCTs to confirm findings
- ➔ Women with HFrEF should get access to aldosterone receptor antagonists whenever possible

Merrill M, Sweitzer NK, Lindenfeld J, and Kao DP (2019) Sex differences in outcomes and responses to spironolactone in heart failure with preserved ejection fraction: a secondary analysis of TOPCAT trial. JACC Heart Fail 7:228–238.

SGLT-2 inhibitors

- Recent investigation of cardiovascular death and hospitalizations for HF in a meta-analysis (> 20‘000 patients)
- Women were more symptomatic and reported worse quality of life
- SGLT-2i driven reduction in primary composite outcomes were more pronounced in men compared to women (OR 1.32; 95 % CI 1.17 to 1.48; p = 0.0002)

Rivera FB, Tang VAS, De Luna DV, et al. Sex differences in cardiovascular outcomes of SGLT-2 inhibitors in heart failure randomized controlled trials: A systematic review and meta-analysis. Am Heart J Plus. 2023;26:10026

Antiarrhythmic drugs

- Women exhibit a higher incidence of QT prolongation and subsequent arrhythmias when given antiarrhythmic and QT- prolonging drugs (e.g. erythromycin, antidepressants
- ➔ Be wary of potential QT-prolonging effects of drugs especially in women

Kurokawa J, Kodama M, Furukawa T, and Clancy CE (2012) Sex and gender aspects in antiarrhythmic therapy. Handb Exp Pharmacol 214:237–263.

Lipid lowering drugs

- Female sex risk factor for most common statin adverse effects: myopathy and new-onset diabetes
- Odds of myopathy increased 2x in women
- New-onset diabetes in a large rosuvastatin study 25% total, but49% in women vs. 14 % in men after stratification by sex
- Important in secondary prevention, but women are less likely to receive stating as recommended for secondary prevention

- ➔ Statin treatment needs to be optimized and there is a need for greater inclusion of females in clinical trials investigating statin (adverse) effects

Mora S, et al. (2010): Statins for the primary prevention of cardiovascular events in women with elevated high-sensitivity C-reactive protein or dyslipidemia: results from the Justification for the Use of Statins in Prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER) and meta-analysis of women from primary prevention trials. Circulation 121:1069–1077. (05.03.2025)

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Last but not least the Physician Patient Interaction is the key for treatment!

· Gender differences in quality of care
· ➔ Patients treated by female doctors were more likely to achieve their LDL-C goals, although they did not receive more statins
· Similar data for blood pressure and glucose goals
· Treated by a male doctor has been associated with lower adherence to pharmacotherapy
· Different communication styles and higher empathy of female doctors?

Journath G, et al. Hyper-Q Study Group, Sweden (2008) Association of physician's sex with risk factor control in treated hypertensive patients from Swedish primary healthcare. J Hypertens 26:
2050–2056
Roter DL, Hall JA, and Aoki Y (2002) Physician gender effects in medical communication: a meta-analytic review. JAMA 288:756–764.

SUMMARY

- Men and women represent distinct in vivo biological systems, primarily shaped by sex differences responses. These responses are influenced by a variety of in pharmacological endogenous and exogenous factors.
- Current challenges aren't simply an arbitrary oversight of women but rather a reluctance to stratify medical science by sex and move beyond the one-size-fits-all approach.
- Gender effects in pharmacotherapy may be more subtle, influencing the physician-patient relationship rather than manifesting primarily at the biological level.
- Given the current evidence, women appear to be more adversely affected by the limitations of modern pharmacotherapy compared to men.

Author:
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Webinar ICH-GCP – 1st announcement

30 June 2025, 12:00 noon to 2:00 pm CET

ICH – GCP revision

Good Clinical Practice (GCP) is the international scientific and ethical standard for the conduct of interventional clinical trials. The ICH E6 Guideline, published in the mid-1990s, established a harmonised understanding of GCP.

New trial designs, new technology and the greater use of different data sources required a comprehensive revision of the guideline. This seminar will familiarise participants with the key aspects of this revision.

Speakers:

Rebecca Stanbrook BPharm (hons), MRPharmS, FFRPS, DipRQA, FRQA

Rebecca is the EFPIA Topic lead for ICH E6(R3) Expert Working Group, the group responsible for rewriting the Good Clinical Practice Guideline, the global standard for the conduct of clinical trials.

Rebecca has worked at a number of pharmaceutical companies in various roles across all aspects of the pharmaceutical industry and as a regulator at the Medicines and Healthcare products Regulatory Agency (MHRA). To date she has over 30 years' experience in the industry or as a regulator.

Gabriele Schwarz, a graduated pharmacist, joined the German Federal Institute for Drugs and Medical Devices (BfArM) in 2001

Gabriele is currently BfArM's GCP Strategy Expert and represents the EU in the ICH E6(R3) Expert Working Group. For more than a decade and a half, until the end of 2022, she was Head of BfArM's GCP Inspection Unit and responsible for BfArM's GCP inspection activities, particularly in the context of international pre-approval inspections coordinated by the European Medicines Agency.

Over the years, she has contributed to the development of a considerable number of European and international guidelines, such as the OECD 'Recommendation on Clinical Trial Governance', the ICH E6(R2) and (R3) Guideline on 'Good Clinical Practice' and the ICH E19 Guideline on a 'Selective Approach to Safety Data Collection in Specific Late-stage Pre-approval or Post-approval Trials'.

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The International Conference on Pharmaceutical Medicine - ICPM 2025 oral presentations abstracts are brought to you by IFAPP TODAY!

We are pleased to present the approved abstracts for the oral presentations at the International Conference on Pharmaceutical Medicine (ICPM) 2025. This year's conference brought together leading experts, researchers and professionals from around the world to share their latest findings, innovations and advances in Pharmaceutical Medicine.

The abstracts featured in this issue represent a sample of topics, reflecting the dynamic and interdisciplinary nature of our field. From landmark research and novel therapeutic approaches to advances in regulatory science, and patient-centred care, these aspects highlight the cutting-edge science, ethics, continued education and thought leadership that define IFAPP community.

We would like to thank the authors for their invaluable contributions and our reviewers for their careful assessment. We are confident that the insights and discussions generated by these abstracts will inspire new ideas, foster collaborations and contribute to the future of Pharmaceutical Medicine.

We anticipate an engaging and enriching experience for the IFAPP TODAY readers who could not attend the 21st ICPM 2025 in Amsterdam.

Varvara Baroutsou
IFAPP President

Title: Intellectual Property and Regulatory Incentives for Orphan Medicines: A Comparative Review of European and US Policies

Conference (on-stage) presentation

Keywords: Orphan medicines, US and EU policies, intellectual property

Authors:
Dr. Julian W. März, M.D., Ph.D., LL.M., J.S.D.
University of Zurich, Faculty of Medicine, URPP Innovative Therapies in Rare Diseases (ITINERARE)

Abstract:
Background
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

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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 6,000+ known rare diseases still lack approved treatment options.

Methods
This presentation compares intellectual property (IP) and regulatory incentives for rare disease R&D in the US and the EU, and outlines current reform initiatives. It draws on pertinent US and EU legal and policy sources, including statutes, regulations, case law, action plans, strategy documents, as well as legislative bills and accompanying explanatory memoranda.

Results
The analysis reveals markedly heterogeneous approaches to incentivizing rare disease R&D between the US and EU. The EU generally provides significantly longer regulatory exclusivity periods and follows a technology-agnostic incentive structure. In contrast, the US employs targeted incentives for specific technologies – such as cell and gene therapies – to support the development of innovative modalities. IP-based incentives face challenges when applied to modern therapeutic modalities, particularly cell and gene therapies. Moreover, current frameworks offer limited incentives for the development of platform technologies, as opposed to standalone therapeutic products.

Conclusion
Current IP and regulatory frameworks have succeeded in stimulating orphan drug development but remain inadequate for addressing the full scope of rare diseases, especially in view of the diverging US and EU approaches. A one-size-fits-all model may not be appropriate across all therapeutic areas – for example, voucher programs may be more relevant than SPCs or regulatory exclusivities for gene therapies. This underscores the need to update orphan drug incentives to reflect the rapid evolution of therapeutic modalities.

Takeaway for the Audience: 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.

Short bio: Dr. Julian W. März, M.D., Ph.D., LL.M., J.S.D., has studied medicine, law, and bioethics in Zurich, Oxford, Regensburg, and Paris. As a researcher, he has worked for the Division of Health Economics at the German Cancer Research Center (DKFZ) in Heidelberg and has been a visiting scholar at the Dutch Center for RNA Therapeutics (DCRT) and the Faculty of Law of the University of Cambridge. His primary research interests include pharmaceutical & biotech patent law, regulatory affairs & research ethics, and pharmaceutical pricing, with a particular focus on RNA-based therapeutics, ATMPs, and AI-enabled innovation. In October 2024, Julian was appointed as a member of the World Health Organization (WHO) Research Ethics Review Committee (ERC) for the 2024 – 2027 term.

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Why your proposal should be 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 the EU shape the future of orphan drug innovation.

Title: Intellectual Property Strategy in Pharmaceutical Medicine

Authors:
Takeshi S Komatani [TAKASHIMA International Patent Office & Kobe University/Doshisha University]

Background
The pharmaceutical industry operates at the intersection of innovation, regulation, and intellectual property (IP) protection. Rapid advancements in precision medicine, biopharmaceuticals, and orphan drug development have significantly reshaped the strategic importance of IP in pharmaceutical R&D. Amid the current data-driven drug development landscape, understanding and effectively implementing IP strategies has become crucial.

Methods
This presentation employs case studies and comparative analysis from leading jurisdictions, including the US, Europe, Japan, and China. We assess key IP strategies such as life cycle management (LCM) of drug patents, integration of regulatory exclusivities (data protection and market exclusivity), and innovative patenting methodologies (strategic patenting of drug formulations, new therapeutic uses, and treatment regimens).

Results
Our analysis highlights the importance of a robust global IP strategy in pharmaceutical patenting. Effective IP strategies enable companies to maximize market access, extend product exclusivity, and mitigate competitive risks. Furthermore, medical affairs play a growing role in knowledge creation, influencing strategic patenting decisions and IP portfolio management. The results indicate that the involvement of medical affairs, R&D section, clinical trial section, and market authorization section are necessary for an effective IP portfolio. In view of this, the author has conducted workshop-style lectures at the PharmaTrain Course at Osaka University for the last couple of years and has observed successful outcomes.

Conclusion
Optimizing IP strategies is vital to navigating complex regulatory frameworks and enhancing commercial success in the pharmaceutical industry. Strategic integration of patent rights with regulatory exclusivities and innovative patenting approaches positions companies to succeed in a highly competitive and dynamic environment, ultimately fostering greater pharmaceutical innovation and market stability. The author proposes establishing an international Working/Study Group/Committee at the IFAPP to enhance international cooperation and collaboration.

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Original Abstract

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. 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 your proposal should be 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.

W*hat the audience will gain from your presentation:*

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.

Short Biography (Bio may be used in conference materials if proposal is accepted):

Dr. Takeshi S. Komatani is a distinguished intellectual property strategist and pharmaceutical medicine expert with over two decades of experience spanning pharmaceutical R&D, patent law, and global IP strategy. Holding a Ph.D. in Pharmaceutical Sciences from the University of Tokyo and an LL.M. in Intellectual Property from Keio University, he bridges the gap between scientific innovation, regulatory frameworks, and IP protection.

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Dr. Komatani has a diverse career background, including preclinical research at F. Hoffmann–La Roche in Switzerland, extensive IP litigation experience in Japan, and strategic consulting for pharmaceutical, biotech, and life science ventures. He specializes in patent portfolio management, pharmaceutical patent litigation, regulatory affairs, and commercialization strategies, particularly for orphan drugs, precision medicine, and AI-driven healthcare technologies. Currently a Litigation-Certified Patent Attorney at Takashima International Patent Office, he also serves as a Visiting Professor at Kobe University and Doshisha University, mentoring future leaders in IP law, entrepreneurship, and pharmaceutical medicine. His expertise is recognized through advisory roles at the Japan Patent Office (IPAS program) and the Ministry of Health, Labour and Welfare (MEDISO program), as well as leadership in international organizations such as AIPPI and WIPO Academy. With a strong passion for bridging innovation and intellectual property, Dr. Komatani continues to shape global pharmaceutical IP strategies while actively engaging in startup mentoring and international policy discussions on pharmaceutical innovation and IP rights.

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