IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

New Year Greeting 2025

Dear members, colleagues and friends,

As we usher in the New Year 2025, I extend my heartfelt wishes to each and every one of you. The past year has been a testament to our collective resilience, innovation and unwavering commitment to advancing scientific knowledge in Pharmaceutical Medicine.

(1)

I would like to pay tribute to Johanna Schenk as a Hero of Pharmaceutical Medicine, whose dedication and contributions have greatly enriched the legacy of IFAPP and increased the impact of IFAPP and the IFAPP TODAY Journal as Editor-in-chief, and I wish Johanna a fulfilling and joyful retirement. Her legacy will continue to inspire us.

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In 2024, we achieved remarkable milestones, reported in the November-December 2024 issue of IFAPP TODAY (number 49), that pushed the boundaries of our purpose-driven goals (2).
As we look forward to 2025, let us continue to embrace the spirit of curiosity and dedication that defines our community.

Albert Einstein once said, "The important thing is not to stop asking questions. Curiosity has its own reason for existing". Let this quote inspire us to excel in ethics and science, asking audacious questions and seeking answers that can advance Pharmaceutical Medicine.

Our goals for 2025 are both ambitious and inspiring:

1. Making ICPM 2025 a success: Focusing on breakthrough developments, exchanging views on critical global challenges in research and development, from research ethics to digital medicine and innovation in healthcare.

2. Fostering collaborative networks: Further strengthen our partnerships with academia, international institutions such as WMA (3) and CIOMS (4), and increase our contributions to global organisations such as ICH (5) and WHO (6), the PharmaTrain Federation, and regulatory authorities such as EMA (7), FDA (8) and others to accelerate scientific progress in drug development.

3. Promoting Pharmaceutical Medicine education and certification driven by technological and scientific advancements: Enhance our webinars and training programmes to inspire the next generation of biomedical scientists, ethicists, data scientists, bioengineers and other specialties on predictive analytics, precision medicine, Medical Technology, and medical devices.

4. Investing in the future of Pharmaceutical Medicine: Welcoming applications for IFAPP Fellowships for the second cycle in 2025, preparing an innovative internship for young professionals to contribute to our projects to gain experience, enhance skills, benefit from IFAPP educational sessions and mentorship from IFAPP members.

5. Increasing public engagement through our Working Groups: Strengthen our efforts to engage patient groups, societal stakeholders and experts in the design, conduct and outcomes of scientific research, thereby fostering greater public contribution to science, patient safety and better health.

May our curiosity lead to new opportunities, inspiring creativity and strengthened partnerships. Together, we will continue to make progress in our quest for knowledge and contribute to a more advanced Pharmaceutical Medicine world.

We will continue to work for IFAPP tirelessly towards a blue horizon and face the New Year with optimism, determination and a clear vision for a brighter future.

I encourage each of you to take an active role in our Working Groups and initiatives and to share your innovative ideas to achieve our common goals.

Together, we can make 2025 a year of extraordinary achievement.

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I am also pleased to announce the IFAPP Fellows Ceremony, to be held during the ICPM 2025 conference in Amsterdam on 9 April 2025. This prestigious event will be the ideal opportunity to honour our distinguished 2024 IFAPP Fellows.

I am additionally delighted to invite you to the 50th Anniversary Celebration of IFAPP, which will take place during ICPM 2025 in Amsterdam on 10 April 2025.

I look forward to seeing you at ICPM 2025 in Amsterdam on 9-11 April 2025 (10). This conference will be a fantastic opportunity to share your professional wisdom and experience, network with IFAPP Fellows, discuss with our member scientists, international speakers and experts, explore the latest advances in our field and celebrate the IFAPP's 50th Anniversary with colleagues.

For more information, visit the ICPM 2025 website at https://icpm2025.com/.
Be there to take part in the IFAPP House of Delegates and General Assembly and share your thoughts and views, either as a National Member Association delegate or as an Individual Affiliate member.

I wish you and your loved ones a very happy, healthy and fulfilling New Year.

Yours sincerely,
Dr Varvara Baroutsou, IFAPP President

References

1. Photo Credit ©Eleni Papadaki /PHOTOPRESS Θ&A Anagnostopouloi
2. https://ifapp.org/journal/november-december-2024-number-49/
3. WMA: World Medical Association
4. CIOMS: Council for International Organizations of Medical SciencesCcc
5. ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
6. WHO: World Health Organization
7. EMA: European Medicines Agency
8. FDA: Food and Drug Administration
9. Note: V. Baroutsou as Microsoft 365 subscriber has full access to the library creative material of stock images
10. https://icpm2025.com/

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Thank You to a Visionary Leader: Dr Johanna Schenk

With immense gratitude, we recognise the extraordinary contributions of Dr Johanna Schenk whose dedication and vision have profoundly shaped Pharmaceutical Medicine and the IFAPP community. As we bid farewell to Johanna in her latest role as Editor-in-chief of the *IFAPP TODAY* Journal, we reflect on the remarkable legacy of a true leader and advocate for Pharmaceutical Medicine. Johanna has been an unwavering force in shaping the field, exemplifying a commitment to excellence, innovation, and collaboration.

Johanna's distinguished tenure as IFAPP President from 2000 to 2002 marked a period of transformation and vision. Her presidency was guided by the theme "The Future is Now," a motto that underscored her forward-thinking approach to Pharmaceutical Medicine. She prioritised global collaboration, fostered deeper involvement of member associations and enhanced IFAPP's international visibility through partnerships with regulatory bodies. Her leadership saw the establishment of key initiatives, including the IFAPP Council for Education in Pharmaceutical Medicine and the Working Party on Ethics in Pharmaceutical Medicine, both of which continue to influence the field today.

As Editor-in-chief of the *IFAPP TODAY* Journal, Dr Schenk brought her visionary spirit and editorial excellence to elevate the publication as a platform for thought leadership and critical dialogue. Her dedication ensured the journal remained a cornerstone of scientific discourse in Pharmaceutical Medicine.

Johanna's legacy lies not only in her achievements but in the inspiration she provided to all who worked with her. Her belief that "the future is bright if we utilise our international network wisely" resonates as a call to action for the next generation of leaders in Pharmaceutical Medicine.

While her departure marks the end of an era, we are grateful that she remains part of our community as a valued supporter and reader. Johanna, we thank you for your unparalleled contributions and hope to carry forward the high standards you set, striving to honour your legacy and vision. You will always be a Hero of Pharmaceutical Medicine to us.

With heartfelt appreciation,
Ghazaleh Gouya-Lechner, Board member and Chair of the Communication Working Group at IFAPP, Board member of GPMed (Gesellschaft fuer Pharmazeutische Medizin, Austria), Head of Gouya Insights, Clinical Development
and all members of the Communication Working Group

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Join Us at the International Conference of Pharmaceutical Medicine in Amsterdam!

Are you ready to connect with the brightest minds in Pharmaceutical Medicine? Join us at the International Conference of Pharmaceutical Medicine, hosted in the iconic Koepelkerk in Amsterdam, a city renowned for its charm and innovation.

When: 9-11 April 2025
Where: Koepelkerk, Amsterdam
Theme: Purpose for Future

This prestigious event promises to be an unparalleled opportunity for professionals, researchers, and thought leaders in the pharmaceutical field to gather, share insights, and shape the future of healthcare.

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Why Attend?

- **World-class Speakers: Hear from renowned experts who are driving innovation and change in Pharmaceutical Medicine. Among others:**

  - **Prof. Steffen Thirstrup**, Chief Medical Officer at European Medicines Agency (EMA)
  - **Prof. Marc Bonten,** Professor of Medical Microbiology and coordinator of infectious diseases and epidemiology at University Medical Center Utrecht
  - **Dr Otmar Kloiber,** Secretary-General of the World Medical Association (WMA)
  - **Prof. Stephen Senn,** Statistical Consultant for the Pharmaceutical Industry.

- **Dynamic Panel Discussions: Engage in thought-provoking conversations on the latest trends, challenges, and breakthroughs in the industry.**
- **Exceptional Networking Opportunities: Connect with international peers, industry leaders, and decision-makers in an inspiring and collaborative atmosphere.**

The Venue

Set in the stunning Koepelkerk, a historical landmark in the heart of Amsterdam, this conference combines cutting-edge content with the charm of a breathtaking venue.
Do not miss this chance to be part of a transformative experience in one of Europe's most vibrant cities.

Register now to secure your spot and take the next step in advancing your knowledge, career, and network in Pharmaceutical Medicine. The Early Bird fees have been extended until 31 January 2025!

Visit our website for more details and registration information: www.icpm2025.com

We look forward to welcoming you to Amsterdam!

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Shaping the Future of Pharmaceutical Medicine in Egypt: A Transnational Education Initiative Led by MEAPP

The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP), in partnership with King's College London (KCL) and Future University in Egypt (FUE), has secured a prestigious Transnational Education (TNE) Exploratory grant from the British Council's Going Global Partnerships program.

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 higher education, science, and Technical and Vocational Education and Training (TVET) globally.

Our project, "A Capacity Building Programme for Enhancing Clinical Research and Medicine Development in Egypt," was selected for its potential merits to address critical needs in the Egyptian healthcare sector. This programme aims to equip Egyptian scientists from various sectors with the necessary skills and knowledge in the field of medicine development.

The project will span over one year, commencing in January 2025. We will kick off the project with an event titled " Shaping the Future: Leveraging Transnational Education and Capacity Building in Pharmaceutical Medicine in Egypt" on 22 January 22 2025. This event will provide an invaluable platform for senior management, executives, dignitaries, and decision-makers to gain a deeper understanding of the programme's significance and its potential to elevate the pharmaceutical landscape in Egypt.

Following the launch event, the first module, "Clinical Drug Development," will commence on 28 January 2025. This will be followed by the "Drug Development Statistics & Data Management" module in May 2025. The final module, "Health Technology Assessment & Pharmacoeconomics," is scheduled for September 2025.

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Dutch EUPATI (1) Fellows Champion Patient Perspectives in Medicine Research and Development

"We're talking crippling side effects like cancer, cardiovascular disease, and diabetes - all because of a kidney transplant that was supposed to save my life. The daily medication I use has side effects I never expected," says Carine Besselink, a Dutch EUPATI fellow who has had kidney disease since childhood. Driven by a commitment to improve her life and those of her peers, Carine was part of the first group of 16 EUPATI NL students in 2019. As a fellow, she now collaborates with the Regulatory Science Network Netherlands, has established a Patient Advisory Board with two other fellows, and speaks at universities and conferences to raise awareness of adverse events caused by treatment.

The most recent group of EUPATI students after graduating from the EUPATI NL programme

EUPATI NL: Equipping patient experts

Since this first group of EUPATI NL fellows graduated, 28 more have completed this intensive programme which lasts over a year and includes five modules on topics crucial for patient advocates. Subjects include non-clinical research, European Medicines Agency (EMA) procedures, and practical fieldwork at pharmaceutical companies, the Medicines Evaluation Board (MEB), and the Dutch Clinical Research Foundation (CHDR). In addition to technical skills, the students also develop professional abilities such as pitching and leadership skills.

Partner Jeroen van Smeden, Education Director at the CHDR and guest lecturer at EUPATI NL, emphasises the programme's transformative impact on all involved *"One of the roads towards better clinical research is through patient advocate participation. Training patient experts to become equal partners is a huge part of that. At the same time, researchers need to see patients as central to their work and realise that involving patient experts is essential. Researchers don't automatically know what patients prioritise, and patients aren't always familiar with the intricacies of clinical research. This programme bridges that gap."*

EUPATI NL collaborates not only with the CHDR, but also with many stakeholders in the Dutch medicine development field, including the MEB, Health-Holland, the University of Applied Sciences Utrecht, HollandBIO, the Ministry of Health, Welfare and Sport, the Dutch Patient Federation, the Dutch Association of Innovative Medicines, and the National Healthcare Institute.

Sanne van Rijn, another EUPATI NL fellow, underscores the programme's impact on her advocacy. Sanne represents families affected by a rare genetic condition, Dutch-type cerebral amyloid angiopathy (CAA), and she notes *"EUPATI NL empowered us to make a meaningful contribution to CAA research. Our input is valued, and bringing the patient perspective enhances every aspect, from study design to participant communication. Still, there is room for improvement in rare disease drug development in the Netherlands, but I see a growing awareness among stakeholders of the need for patient expert involvement."*

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INVOLV and the value of patient advocate training

The EUPATI NL programme is developed and executed by INVOLV, a Dutch non-profit organisation committed to empowering patients to engage as informed and equal partners in health research and development. Saskya Angevare, a fellow alumna of Carine Besselink and now the EUPATI programme coordinator, explains INVOLV's philosophy *"We at INVOLV believe that equipping patient advocates with knowledge and skills is essential for them to gain a meaningful role in drug development. Through the INVOLV Academy, we provide advocates with the tools they need to actively contribute."*

In addition to supporting patient advocates, the programme helps them grow their networks and roles in the Dutch drug development landscape. INVOLV offers training opportunities to all Dutch advocates through EUPATI NL, expanding the reach of this knowledge.

INVOLV's mission for lasting impact

INVOLV's broader mission reflects a vision for a more inclusive and collaborative approach in health research. CEO Dries Hettinga explains *"Patient involvement is crucial for improving healthcare, research, and quality of life for people living with chronic conditions or disabilities. At INVOLV, we guide, train, and advise all stakeholders, patients, researchers, and healthcare providers, on working together effectively."*

To strengthen patient participation, INVOLV offers programmes like peer-to-peer coaching which pairs researchers with advocates, and a so-called 'Kickstarter' to help research scientists incorporate patients' expertise. In collaboration with the University Medical Center Groningen, INVOLV has also developed a comprehensive training module for researchers.

Working towards a Better Future

INVOLV envisions a future where people with medical conditions can live without limitations. For Carine and her fellow advocates, each step counts towards a future where adverse events are minimal, and quality of life is prioritised. *"We may not get there overnight," Carine reflects, "but every tool we have helps us to make changes that improve our lives. Even if we're aiming for New York and end up in Paris, it would still be worth it."*

Over the next few years, INVOLV will continue to train patient advocates through EUPATI NL. With each graduating class, a growing number of patient experts will contribute to fields ranging from rare cancers to mental health issues, promising more patient-centred approaches to medicine development in the years ahead.

Connect with EUPATI NL

INVOLV hopes that more professionals will involve patient experts in their respective fields. A great way to connect with EUPATI NL fellows is through EUPATIconnect, a European platform where patient experts and researchers can engage and collaborate. Visit https://connect.eupati.eu/ to get started.

(1) EUPATI: European Patient Academy on Therapeutic Innovation

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The first group of EUPATI Netherlands students during a working visit to Janssen Pharmaceuticals (Johnson & Johnson)

A group of students and fellows on a field trip to the Dutch Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen) – the official and sole Dutch governmental body responsible for granting marketing authorisations for medicines under the Medicines Act.

Authors:
Judith Winnen, BSc, Communication Advisor at INVOLV
Dr Sophie Kemper, Advisor on Patient Participation in Research at INVOLV

GPMed's New Circle for Study Coordinators and Study Nurses

As a scientific forum for physicians, scientists and other healthcare professionals, GPMed, the Society for Pharmaceutical Medicine in Austria, also aims to network and represent the interests of study coordinators and study nurses. GPMed has therefore established a fourth circle in addition to the three existing circles - Clinical Operations Circle, Medical Affairs Circle and Research Innovation Circle: The Study Coordinators and Study Nurses Circle aims to bring together and network clinical study coordinators and clinical study managers. Ingeborg Brandl, Head Study Nurse at the Breast Health Study Team, Department of Gynaecology, Medical University of Vienna, and Sabine Embacher-Aichhorn, Head of the Competence Centre, for Clinical Studies (KKS), Medical University of Innsbruck, lead the new circle.

PHARMAustria, a professional journal for pharmacy and Pharmaceutical Medicine, spoke with both about their goals and visions for the new GPMed Circle.

GPMed
GESELLSCHAFT FÜR PHARMAZEUTISCHE MEDIZIN E.V.

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PHARMAustria: How did the new GPMed Circle come about? What will it focus on?

Ingeborg Brandl: It was set up at the request of Bernhard Mraz, President of GPMed, because study nurses and study coordinators did not have a platform where they could exchange ideas and information. The goal is to implement standardised training with a uniform level throughout Austria. The primary aim is to create a platform for questions which will then be used to develop topics for further work.

Sabine Embacher-Aichhorn: Most study coordinators and study nurses in Austria work in precarious employment relationships. Their contracts are mainly concluded for 6 or at best 12 months only, the study coordinators and nurses learn often only a few days or weeks before the end of the contract whether it will be prolonged or not, and as soon as the chain contract regulation is exhausted, further employment at the university is no longer possible. In addition, salaries tend to be poorly graded, depending on the possibilities of the individual study groups. In order to improve these conditions, a platform is needed where study coordinators and study nurses can exchange ideas and present themselves to the outside world. I was therefore happy to follow GPMed's suggestion to set up my own Circle. Some institutions have already made changes to working conditions, for example by offering permanent employment and by differentiating salaries according to qualifications. At the Medical University of Innsbruck's Competence Center for Clinical Trials (KKS), for example, this led to a significant increase in the number of job applications for study coordinators - from 3 at the end of 2022 to 23 in August 2024!

PHARMAustria: What are the Goals of the Study Nurse and Coordinator Circle?

Brandl: In my opinion, the aim is to improve the networking among each other in order to get an overview of the work in the individual study centres. Our vision is standardised training and equal pay throughout Austria.

Embacher-Aichhorn: Our goal is to improve the framework conditions for study coordinators and study nurses at all institutions in Austria. We are also striving for standardised training, the focus, duration and components of which need to be defined. In addition, the exchange between these professional groups with other related professions should be promoted. We would be very pleased to have the support of the pharmaceutical companies as they would benefit from the improved framework conditions we are aiming at; for example, long-term study coordinators and study nurses would also benefit the pharmaceutical industry with their knowledge and as permanently available contacts.

PHARMAustria: How are the goals to be achieved?

Brandl: Implementation will certainly not be possible overnight. The first step is to publicise the Circle and motivate colleagues to participate in order to build a foundation. Then we can try to achieve a standardised level through further training and discussions. Nevertheless, these are visions for the future. First, we have to find colleagues who want to take part. Then we can talk about the rest.

Embacher-Aichhorn: I also think that informing all study coordinators and study nurses is an important first step. It is crucial to communicate what is possible, to present best-practice examples of framework conditions, so to speak, in order to initiate changes in the system.

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In addition, the Study Nurses and Study Coordinators Circle should be coordinated with the Clinical Operations Circle of GPMed in order to inform the other stakeholders about the important role that study coordinators and study nurses play. As I said, promoting dialogue is one of the main objectives of our Circle. In this context, I would like to draw your attention to the biennial umbrella symposium for clinical trials in the DACH region (Germany, Austria and Switzerland). This year it took place in Berlin, in 2026 the venue will be in Innsbruck, probably in September. Training for study coordinators and study nurses will also be an important part of the event – and, of course, dialogue will be at the forefront!

PHARMAustria: Thank you very much for this interview!

Conclusion: GPMed has launched a new 'Circle' specifically for study coordinators and study nurses to address their needs, support networking, and improve their working conditions in Austria. Under the leadership of Ingeborg Brandl and Sabine Embacher-Aichhorn, this platform aims to provide a space for professional exchange and to campaign for standardised training, greater job security and fairer pay. Future goals include the creation of a uniform training framework, the strengthening of inter-professional dialogue and the presentation of best practices in order to enhance the profession and promote long-term cooperation with the pharmaceutical industry.

Sabine Embacher-Aichhorn started her journey in Clinical Research in the pharmaceutical industry and enjoyed being a manager while learning Clinical Operations from scratch in an era of industrial expansion and emerging regulations acting together to lift Clinical Research to today's level.

In 2006 Sabine Embacher-Aichhorn joined the Medical University of Innsbruck and built, step-by-step, a service offer for clinical research scientists that spans the entire scientific value chain: from planning a trial, organising the resources needed, to study execution with all operational aspects to reporting and dissemination of results, and managing alliance partners.

Since then, the Competence Center for Clinical Trials (KKS), where, initially, Sabine covered all service offers alone, grew to today's headcount of more than 70 specialists. The Medical University of Innsbruck's "in-house CRO" now covers academia-driven clinical trials on cutting edge research questions as well as the contribution to large industry-sponsored global clinical trials of ultra-high commercial value. Years of experience with hundreds of trials enable professional services to research work with medicinal products of all kinds but also with medical devices of all types. The level of involvement with trials spans from advice to provision of temporary team resources for study conduct such as study coordinators who assist investigators executing the trial, to project management or specialised services, e.g. negotiating study budgets with external sponsors on behalf of principal investigators, and contract management.

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Ingeborg Brandl, MSc, has been a qualified health and nursing professional since 1991. She started her career at the General Hospital of Vienna in gynaecological oncology and moved to the Medical University of Vienna as a study nurse in 2004.

In the following years she built up the study centre at the Department of Senology. During her career she supervised phase 2, 3 and 4 studies as well as academic studies according to AMG and MPG (medicinal product and medical device law).

In 2010 she completed her Master of Science in Advanced Clinical Research at Kepler University in Linz. Her responsibilities include patient care and monitoring, clinical trial coordination, study drug administration, documentation and data management, data validation, quality control and compliance, interdisciplinary communication, and ensuring patient safety.

Her work contributes significantly to the success of clinical trials and ensures that patients are involved in research in a safe and ethical manner.

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The European Young Person's Advisory Group Network (eYPAGnet) provides a platform for children and young people to have a voice across Europe, share their opinions, and apply their experience to a variety of issues in clinical trials, such as relevant endpoints, protocol design, formulations, age-appropriate information, and patient tools.

The majority of YPAGs include young people aged between 8-19 years (although some groups have older young adults up to the age of 23) who are patients, regular attenders at the hospital, and/or have an interest in science, healthcare, and children's rights. YPAGs are predominantly facilitated by a professional involved in a clinical research facility, children's hospital, or academic institution.

eYPAGnet provides a centralised point of contact and creates a platform in which investigators can access the opinions of children and young people in a manner that is regulated with standard contracts, confidentiality agreements, agreed payments for services, and services that are ethically sound.

- To improve the capacity of collaboration between children, young people, and stakeholders who participate in the research process and development of innovative drugs.
- To promote the planning and development of clinical research initiatives for children at a European level.

SPEAKERS

Begonya Nafria
eYPAGnet Steering Committee member,
Head of the Patient Engagement
in Research at SJD Barcelona
Children's Hospital

Ségolène Gaillard
eYPAGnet Steering Committee member,
PPI expert of the Hospices Civis du Lyon

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Strategic Transformation: The Growing Role of Medical Departments in the Pharmaceutical Industry

amife ASOCIACIÓN DE MEDICINA DE LA INDUSTRIA FARMACÉUTICA

The Spanish pharmaceutical industry is witnessing a substantial transformation in its medical departments which have evolved from simple support areas to essential strategic pillars. According to a recent study carried out by AMIFE, the Spanish Association of Pharmaceutical Medicine, and published in the journal 'Pharmaceutical Medicine', the number of professionals in these departments has increased significantly, highlighting their growing importance in strategic decision-making. This shift not only drives greater patient-centred care and operational excellence, but also strengthens the industry's ability to innovate and improve access to crucial treatments.

In recent years, medical departments within the pharmaceutical industry have undergone a remarkable evolution from being support areas to becoming crucial strategic areas for the success of companies. A recent article published in the journal 'Pharmaceutical Medicine' (1) coordinated and written by medical directors, members of AMIFE, reveals that the number of professionals in the medical departments has increased significantly, driving the creation of new areas of knowledge focused on patients and excellence in the execution of activities. This is the first time that an in-depth study has been carried out on the roles, responsibilities and analyses of the professional profiles of Pharmaceutical Medicine in the industry.

The study consisted of an online survey with 25 questions grouped into four blocks (structure, medical management, training, and activities and responsibilities). Medical departments of the Spanish pharmaceutical industry of different sizes and scope were invited to participate, of which some 30 companies participated.

In previous years, the medical directors' role was that of a professional specialised in Pharmaceutical Medicine whose main objective was to support the various areas of the company for the generation of scientific evidence, development and making available safe and effective medicines to society. Their functions ranged from being involved in research and innovation of new drugs to the management of clinical trials, pharmacovigilance, regulatory compliance and providing medical advice, among others. This profile has evolved in recent years, currently acquiring a much more strategic role, with greater weight on the decision-making process of the pharmaceutical companies.

This transformation is due to a variety of factors including the increasing complexity of the pharmaceutical industry, the need for evidence in actual clinical practice to support the efficacy of medicines, and the increasing importance of patient-centred care. Currently, the medical director plays a fundamental role in the company's strategic decision-making, managing relationships with key opinion leaders, with centres of excellence in research or with key players in our healthcare system.

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X-ray of Medical Departments in Industry

The results of the study as mentioned above indicate that 93.3% of the professionals work in international departments with a strong presence of highly qualified medical directors and managers, many of them with doctorates. This transformation not only highlights the growing importance of these departments but also underscores their strategic role in guiding the industry towards a more patient-centric approach. Medical directors are usually medical graduates (86.2%) with doctorates (34.5%), and medical managers are mainly graduates in medicine (77.8%) and pharmacy (66.7%). Professionals in these roles range from experienced medical directors to managers with 6-20 years of experience in the sector.

The medical departments in the pharmaceutical industry began to operate in Spain from the 1970s (AMIFE was founded in 1975), and their main function was to provide general advice for the development and preparation for the marketing of the drug based on the clinical knowledge of the medical professionals, especially with special dedication to clinical trials. In the late 1970s and early 1980s, the development of medicinal drugs began to give more importance to preventive aspects and the curative efficacy of the disease, an area that had escaped the pharmaceutical researchers so far. In this way, medical doctors in the pharmaceutical industry went on to direct the research of the drugs and the corresponding clinical trials. From the 1990s, Pharmaceutical Medicine professionals not only carried out this work of consulting and directing research, but also took responsibility for the pharmacovigilance of the drugs and, in the last decade, given the complexity of access to reimbursement for these by the National Health System, including market access and relations with patient organisations.

Today's Profile of Professionals in Medical Departments

The AMIFE study details that, now, medical departments actively participate in the dissemination and generation of scientific evidence, collaborating closely with medical, academic and scientific societies. In addition, medical advisors design and implement medical affairs plans and interact with other departments such as marketing, regulatory affairs, and market access, as well as with national and international thought leaders.
The study shows considerable variability in the structures and functions of medical departments, depending on the size and scope of the companies. This diversity reflects the adaptability and innovation capacity of medical departments to meet complex and dynamic challenges.

With these changes, medical departments not only improve the quality of pharmaceutical products and services but also strengthen the strategic position of companies in an increasingly competitive global market. This development underlines the importance of investing in talent and continuous training to maintain and enhance growth. The evolution of medical departments marks a milestone in the pharmaceutical industry, consolidating them as essential pillars for the development and implementation of strategies aimed at patients' well-being and operational excellence.

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Reference:
1) Pharmaceutical Medicine (2024) 38:241–250 https://doi.org/10.1007/s40290-024-00517-y

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55th Annual Convention of the Philippine College of Pharmaceutical Medicine

The 55th Annual Convention of the Philippine College of Pharmaceutical Medicine (PCPM) was held on 28 November 2024. The theme was “Preparing for a Future Ready Pharmaceutical Medicine Physician”, and, at the beginning of the conference, IFAPP representatives Dr Varvara Baroutsou, IFAPP President, and Professor Kotone Matsuyama, Chair of the Ethics Working Group, participated in the IFAPP session.

First, Dr Varvara Baroutsou gave a keynote speech on the “Changing Landscape of Pharmaceutical Medicine” in which she outlined the implications of the recent revisions to ICH E6R3 (1) and the Declaration of Helsinki and the radical changes in the Pharmaceutical Medicine environment brought about by the rise of advanced technologies such as Artificial Intelligence and Real World Data. IFAPP's contributions to activities such as the update of the 2024 Declaration of Helsinki, the International Congress on Pharmaceutical Medicine in Amsterdam in April 2025 (ICPM2025), the IFAPP Fellowship Programme, and PharmaTrain Syllabus V3.0 of April 2024 (2) were also presented.

Following the keynote speech, IFAPP Ethics Working Group Chair Professor Matsuyama made a designated remark. She commented that it is important not only to promote research governance and review in line with the characteristics of the region, but also to maintain diversity and not to compromise ethical principles.
The next speaker was Dr Jacinto Blas V. Mantaring III, Professor of Clinical Epidemiology and Clinical Professor of Paediatrics. Dr Mantaring gave his feedback in response to Dr Baroutou's keynote speech. In his comments, he introduced the anticipated revisions of ICH E6R3 and the Declaration of Helsinki, which have promoted patient and public involvement and diversity, and are very inclusive revisions, as they relate to ethical principles.

The WHO benchmarking tool (3) was also mentioned, and there was a reference to the role of the ethics review committee in terms of the governance of research institutions, the importance of research, and the promotion of research justice. Dr Mantaring also mentioned the WHO benchmarking tool, but the core of the research governance is the ethics committee within the institution. This is what the Declaration of Helsinki says.

There was a lively discussion with comments and questions from the audience about the appropriateness of using placebo and the importance of ethical reviews.
At the end of the event, the PCPM presented certificates of appreciation to the participating speakers.

Author: **Prof. Kotone MATSUYAMA**, Chair of the Ethics WG, IFAPP

References/Abbreviations

1) ICH_E6(R3)_DraftGuideline_2023_0519.pdf
2) Pharmatrain Syllabus V03 : https://www.pharmatrain.eu
3) WHO Global Benchmarking Tools for evaluation of national regulatory systems https://www.who.int/tools/global-benchmarking-tools

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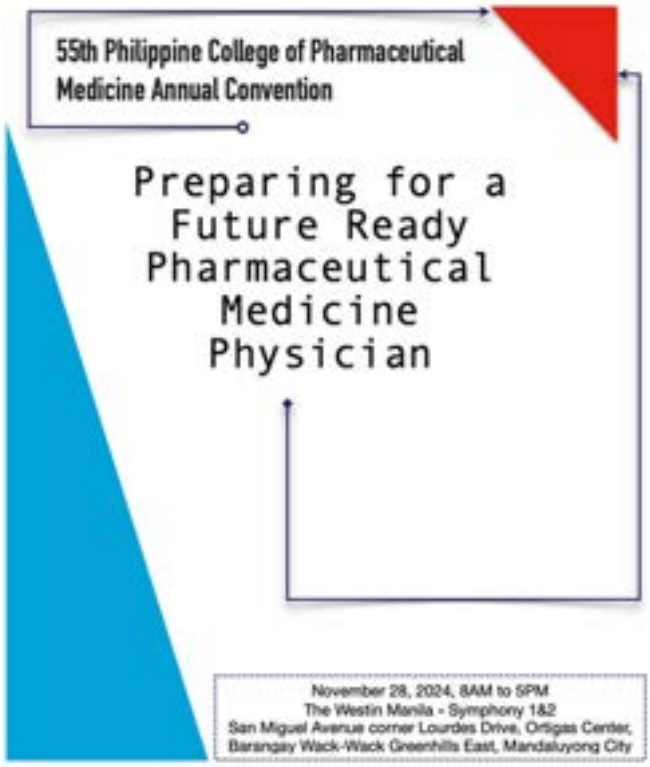

55th Philippine College of Pharmaceutical Medicine
Annual Convention

Preparing for a Future Ready Pharmaceutical Physician

November 28, 2024
The Westin Manila - Symphony 1 & 2
San Miguel Avenue corner Lourdes Drive
Ortigas Center, Mandaluyong City
Philippines

8AM REGISTRATION
830AM OPENING CEREMONIES

9AM IFAPP FORUM:
"Changing Landscape of Pharmaceutical Medicine"

The World Medical Association has recently adopted the revised Declaration of Helsinki marking its 60th year since its initial adoption. While the ICH GCP R3 is currently in Step 3. The International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine will share about the changing landscape of Pharmaceutical Medicine focusing on updates on these important guidance documents.

Dr. Varvara Baroutsou
IFAPP President

Professor Kotone Matsuyama
IFAPP Ethics WG Chair

Reaction: Dr Jacinto Blas Mantaring III
Philippine Health Research Ethics Network, Chair

11AM DOST-PCHRD FORUM:
"Philippines as Center of Excellence for Clinical Trials"

The Philippine Council for Health Research and Development is one of the sectoral councils of the Department of Science & Technology. It is the national coordinating body for health research and has been the vanguard to ensure access to safe and effective health technologies at the height of the COVID 19 pandemic. The Council will present its activities and plans relating to private-public opportunities to forward the Philippines as the Center of Excellence for Clinical Trials and other related programs including HTA and AI in Health and Research.

Dr. Jaime Montoya
Executive Director III, DOST-PCHRD

OPEN FORUM

Afternoon Session

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Highlights of the 2024 Swiss Symposium in Pharmaceutical Medicine

Title: Special Populations in Drug Development and Clinical Care: Across the Entire Life Span from Paediatrics to Geriatrics

This year's Swiss Symposium in Pharmaceutical Medicine, organised by SGPM (1) and ECPM (2), again took place at the Musikschule Florhof in Zurich on 27th November 2024. It covered the multiple facets of drug development from neonates to geriatric patients.

After welcome addresses from the SGPM President Martin Traber, the DGPharMed (3) President Peter Schueler, and the IFAPP (4) President-elect Eric Klaver, the opening talk provided a very comprehensive and detailed overview of ***Ethical Considerations for Clinical Trials Involving Vulnerable Groups and Individuals*** *(Julian Maerz, Institute of Biomedical Ethics and History of Medicine, University of Zurich; ITINERARE (5))* with a focus on the WMA (6) Declaration of Helsinki and the concept of vulnerability, and its 2024 updates. He also highlighted the international ethical guidelines elaborated by CIOMS (7).

This introductory talk was followed by a fascinating presentation on ***Developmental Pharmacology and Pharmacometrics to Facilitate Neonatal and Paediatric Drug Development*** *(Verena Gotta, Children's Hospital, UKBB (8)*, Basel) by pointing out the challenges in paediatric pharmacology, the age-dependent physiology and pharmacology. The take-home message was that developmental pharmacology and pharmacometrics can facilitate paediatric drug development and rational clinical drug use. Collaborative efforts between academia, pharma, and hospitals are key to bring child-appropriate formulations and therapeutics to paediatric patients.

The following presentation dealt with ***Clinical Trials in Children*** with a special focus on the success story of Trikafta® (Elexacaftor, Tezacaftor, Ivacafator), a treatment reducing both the need for lung transplants and the mortality rate in cystic fibrosis *(SwissPedNet President Matthias Baumgartner, Children's Hospital, Kispi, Zurich).*

SwissPedNet (9) is a research network of twelve clinical paediatric hubs throughout Switzerland. Its mission is to facilitate the conduct of paediatric clinical trials, pursue and adopt development and innovation in clinical science, to provide training opportunities for young paediatric researchers and to promote continuous learning. The focus lies on important paediatric problems such as obesity, cancer, chronic respiratory diseases and infectious diseases. The SwissPedNet Lighthouse Project deals with the procedure development for the detection of rare diseases in critically ill children.

Two members of Swissmedic, the Swiss authority responsible for the authorisation and supervision of therapeutic products (Cornelia Bigler and Jeanette Bachir), spoke about ***Swissmedic's Regulatory and Clinical Considerations on Paediatric Investigation Plans.***

There are unmet medical needs in the paediatric population which is very heterogeneous as can be seen in the simple example of body weights ranging from about 0.5 kg to over 100 kg. Paediatric investigation plans are important to show evidence of the quality, safety and efficacy before using a product in children and to ensure that medicines for children are authorised for such use with age-appropriate formulations.

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As of 2019, there is an obligation to develop and submit a paediatric investigation plan in Switzerland and to carry out studies for paediatric use on the basis of the EU Regulation. This is necessary for new authorisations of medicinal products containing new active substances as well as for their extensions of indications, additional pharmaceutical forms and administration routes. Swissmedic also accepts paediatric investigation plans or waivers/class waivers approved by the FDA (10) and/or the EMA (11). The incentive is a 6-month extension of an existing supplementary protection certificate (SPC). Since 2019 Swissmedic has issued 89 confirmations.

The next talk on ***Gender Pharmacology/Medicine*** *(Carolin Lerchenmueller, Gender Medicine, University Hospital Zurich)* highlighted the differences between men and women and how male patients have been favoured in clinical trials and medical practice, both with regard to numbers included in studies and also in terms of diagnosis and acknowledged symptoms in practice.

There are sex differences in pharmacokinetics and pharmacodynamics. A well-known example is the female version of cardiovascular diseases.

All these considerations have now been taken into account by ICH (12): sex-disaggregated information on pharmacokinetics has to be provided for new substances, dose-response studies must be conducted for each sex. Study populations in clinical trials must represent the sex distribution for a disease in the risk population, and analyses should be planned and carried out for both sexes.

After a ***musical intermezzo*** and the lunch break a thrilling and unexpected success story titled ***Family Planning:Ocrevus® during Pregnancy and Lactation*** was described *(Noemi Pasquarelli, Hoffmann-La Roche)*. Women with MS are particularly at risk of relapses post-pregnancy, making it a key consideration for maternal disease management. Ocrevus® (Ocrelizumab) has a relatively long half-life, and effective contraception while receiving Ocrevus® and 12 months after the last dose was recommended. Yet, women with MS taking Ocrevus® became pregnant but no adverse pregnancy outcomes were observed.

Including ***Geriatric Population in Clinical Trials*** was the title of the next presentation *(Angélique Sadlon, University Psychiatric Clinics, Basel)*. In 2014, a review of clinical trials (consortium of nine countries) showed an under-representation of older adults in clinical trials (PREDICT study).

In 2022, data from 166 clinical trials (229 558 participants) for 44 new drug applications and biological license applications showed that the most consistent finding was the limited enrolment of the oldest age groups, namely those 75 years and above for type- 2 diabetes and non-small cell lung cancer, and 80 years and above for non-valvular atrial fibrillation, stroke prevention, insomnia, heart failure, and osteoporosis (13).

There is also a definition problem as *geriatric population* and *older population* are not necessarily the same:

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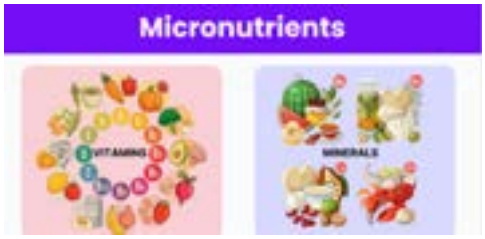
Older people have the right to access evidence-based treatments, and their inclusion in clinical trials prevents discrimination. The safety of clinical trials must be ensured and outcome measures should be relevant for older people. There must be legal requirements and patient education on clinical trial participation must be optimised.

A talk on ***Nutrigenomics: Interventions for the Aging Population*** (*Jorg Hager, Nestlé Institute of Health Sciences, Lausanne*) followed.



(14) Essential micronutrients decline with age due to environmental (e.g. decreased nutrient intake) and biological reasons, decreased absorption (e.g. vitamin B12) or synthesis (e.g. vitamin D), and a decrease in cellular and metabolic turnover, as well as due to genetic factors. Mediterranean diets are the gold standard for healthy eating and are rich in plant-based foods, herbs and spices. Mitochondrial dysfunction is a hallmark of the biological factors contributing to physical decline during aging. Plant-derived compounds such as Oleuropein and Quercetin act synergistically to improve mitochondrial Ca2+ metabolism and restore dysfunctional chondrocyte function as they protect from joint disability progression and limit pain in a pre-clinical model.

Balanced, mostly plant-based diets are a pillar of primary prevention for chronic diseases. Genetic-marker based dose-response models are pragmatic tools for guiding nutrition recommendations. There is a ten-year estimated gain in life expectancy after a shift from unhealthy to longevity-associated dietary factors at age 40 (15).

The symposium ended with an elaborate overview on ***Legal Considerations of Clinical Testing in Vulnerable Populations*** *(Brigitte Tag, Faculty of Law, University of Zurich)*.

Universität Zürich[UZH] Faculty of Law

The historical and legal backgrounds of the current legal situation were presented as in the past, there was abuse of vulnerable populations through medical research with medical experiments involving prisoners, orphans, patients in medical institutions and soldiers. A paradigm shift happened in the 1980s with a regulatory focus on the protection of vulnerable populations with increased inclusion of these groups of people, as human research was recognised as a source of innovative treatments (principle of non-discrimination).

The Declaration of Helsinki was adopted in 1964 followed by the International Covenant on Civil and Political Rights (UN-Treaty II; 16) with the prohibition of research on human beings without consent (Article 7 Sentence 2 UN-Treaty II) in 1966, the adoption of the Convention on Human Rights and Biomedicine in 1997, the Additional Protocol to the Convention on Human Rights and Biomedicine in 2005, and the revision of the Declaration of Helsinki in 2024.

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The Swiss legal and regulatory situation was also presented: the Convention on Human Rights and Biomedicine was enacted in 2008, Article 118b of the Swiss Constitution on research on human beings was approved by the Swiss people and the cantons in 2010, and in 2014 the Enactment of the Human Research Act, and, in particular, the Human Research Ordinance came into effect.

Authors:

Dr. med. Brigitte Franke-Bray, Consultant in Pharmaceutical Medicine, Member IFAPP Communication Working Group

Dr. med. Jean-Marc Hoffmann, Co-Head Clinical Research Ward, Clinical Trials Center, University Hospital Zurich

Dr. med. Raoul-Dominique Giger, Pricing & Market Access Manager, Sanofi-Aventis (Schweiz) AG

Dr. med. Alexandra Kundert, Medical Affairs Scientist Oncology, Pfizer AG

Abbreviations and References:

SGPM: Swiss Society of Pharmaceutical Medicine
ECPM: European Center of Pharmaceutical Medicine
3) DGPharMed: German Society of Pharmaceutical Medicine
4) IFAPP: International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine
5) ITINERARE: Innovative Therapies in Rare Diseases
6) WMA: World Medical Association
7) CIOMS: Council for International Organizations of Medical Sciences
8) UKBB: University Children's Clinic of Basel
9) SwissPedNet: Swiss Research Network of Clinical Paediatric Hubs
10) FDA: US Food and Drug Administration
11) EMA: European Medicines Agency
12) ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for 12) S W Johnny Lau, Yue 13) Huang, Julie Hsieh, et al. Participation of Older Adults in Clinical Trials for New Drug Applications and Biologics License Applications From 2010 Through 20192022 Oct 3;5(10):e2236149
14) https://examples.com/biology/micronutrients.html
15) modified from Global Burden of Disease study group, 2017, Fadnes et al., Nature Food 2023
16) UN: United Nations

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Summary of the IFAPP Webinar on 'Artificial Intelligence in Drug Development' held on 21 November 2024

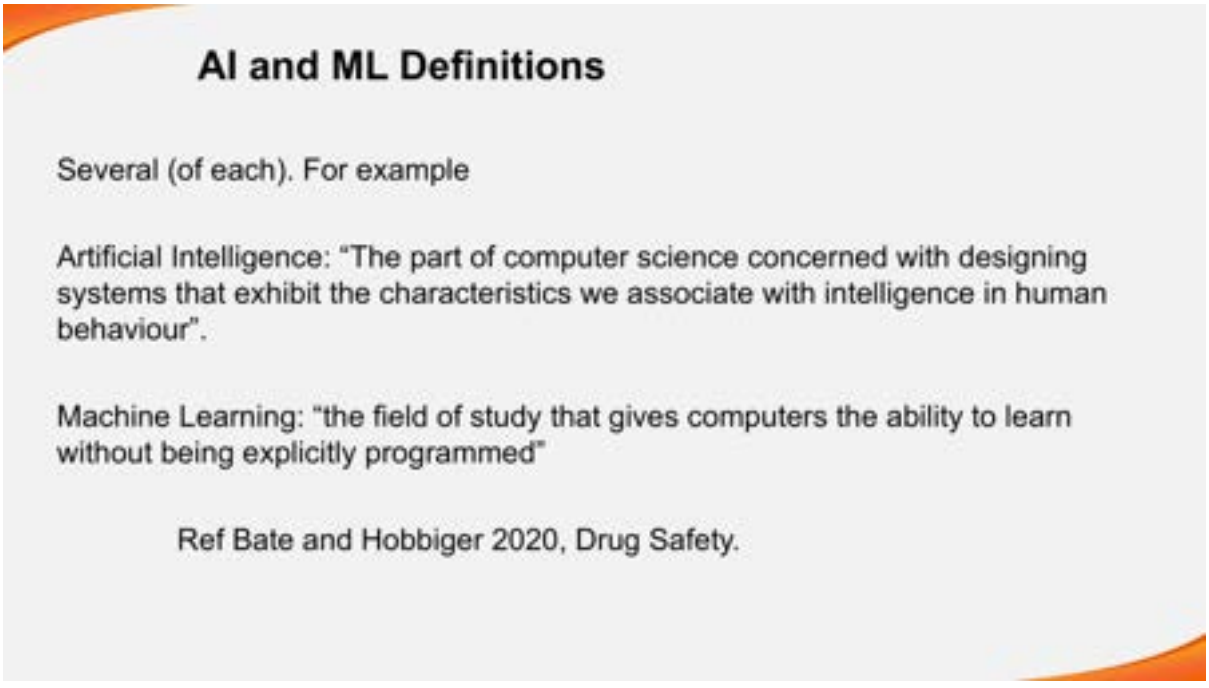
Moderator: **Birka Lehmann**, IFAPP ECWG (Education and Certification Working Group)
Introduction: **Annette Molle**t, ECPM Managing Director & Head of Education and Training
Speaker: **Andrew Bate,** Vice President & Head of Safety Innovation & Analytics GSK
Panellists: **Brian Edwards**, Vice President ISOP (International Society of Pharmacovigilance)
Eirini Chatzopoulou and **Nikos Tsokanas**, EL.E.F.I./IFAPP Pharmacovigilance Group

Machine learning (ML) has been used in assessing the safety of medicines, i.e. Pharmacovigilance (PV), for many years. Challenges are multiple and include the reliance/use of sparse data, validation frameworks and tools, methods and processes as well as explicit and harmonised regulatory guidance.

To advance PV and use automation capability for patients' safety, PV needs to be reconsidered fundamentally, not just superimpose AI/ML on antiquated systems, processes and frameworks, where only limited value and impact will be gained.

Brian Edwards gave a short introduction regarding the responsibilities of the different stakeholders in the PV system and pointed out the importance of giving AI in post-market monitoring the adequate place with regard to the well-being of the patient.

Andrew Bate set the frame by giving clear definitions for:



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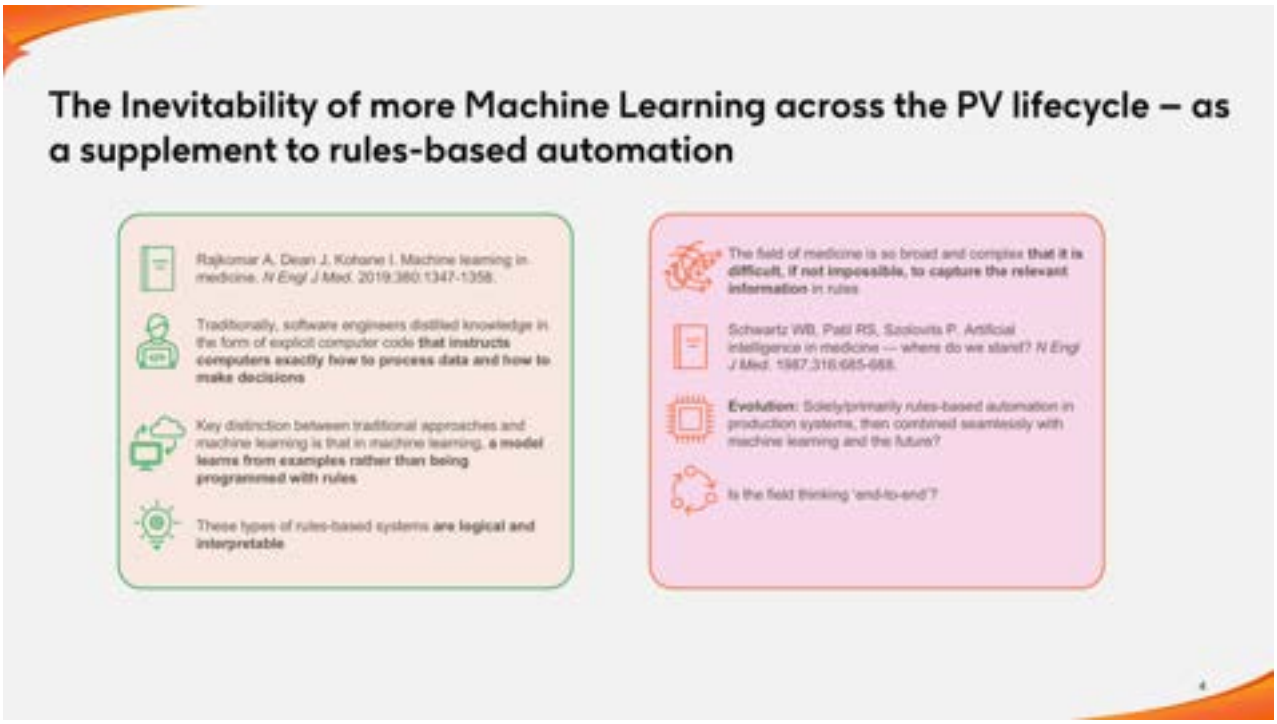
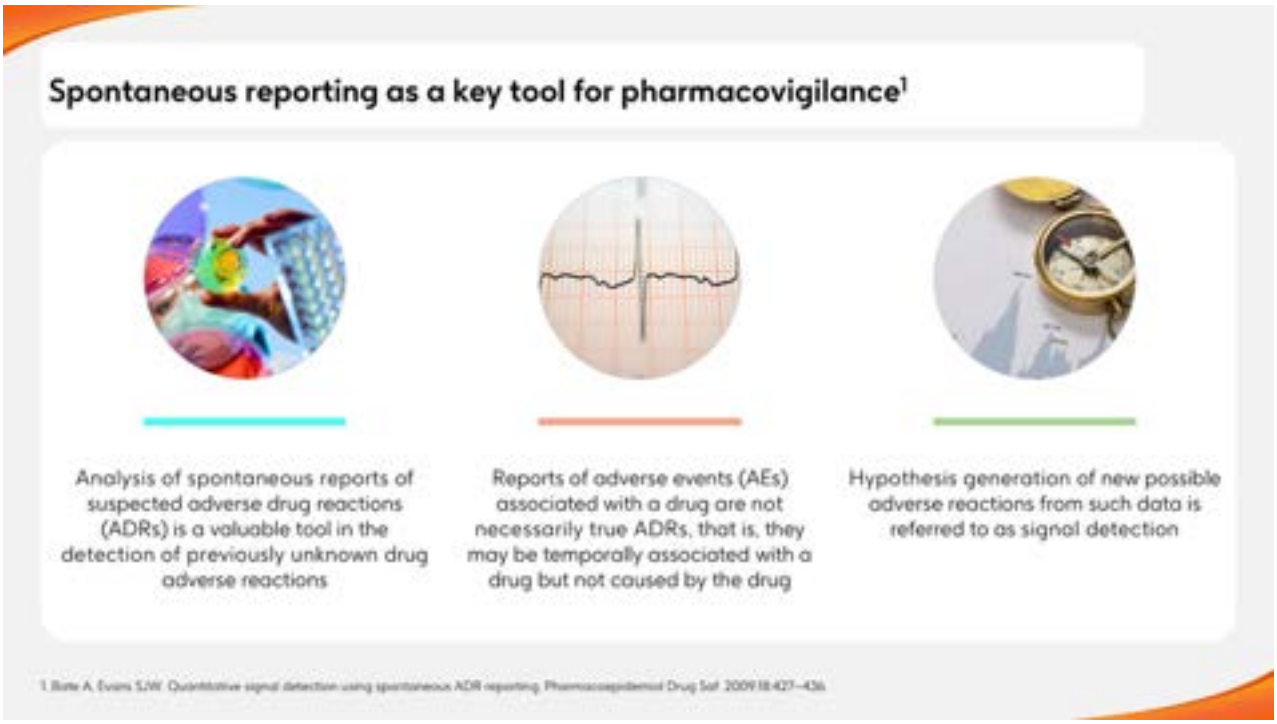
He then gave an excellent overview on why new approaches are necessary:



Due to the challenges of handling e.g. spontaneous reporting new techniques are needed:



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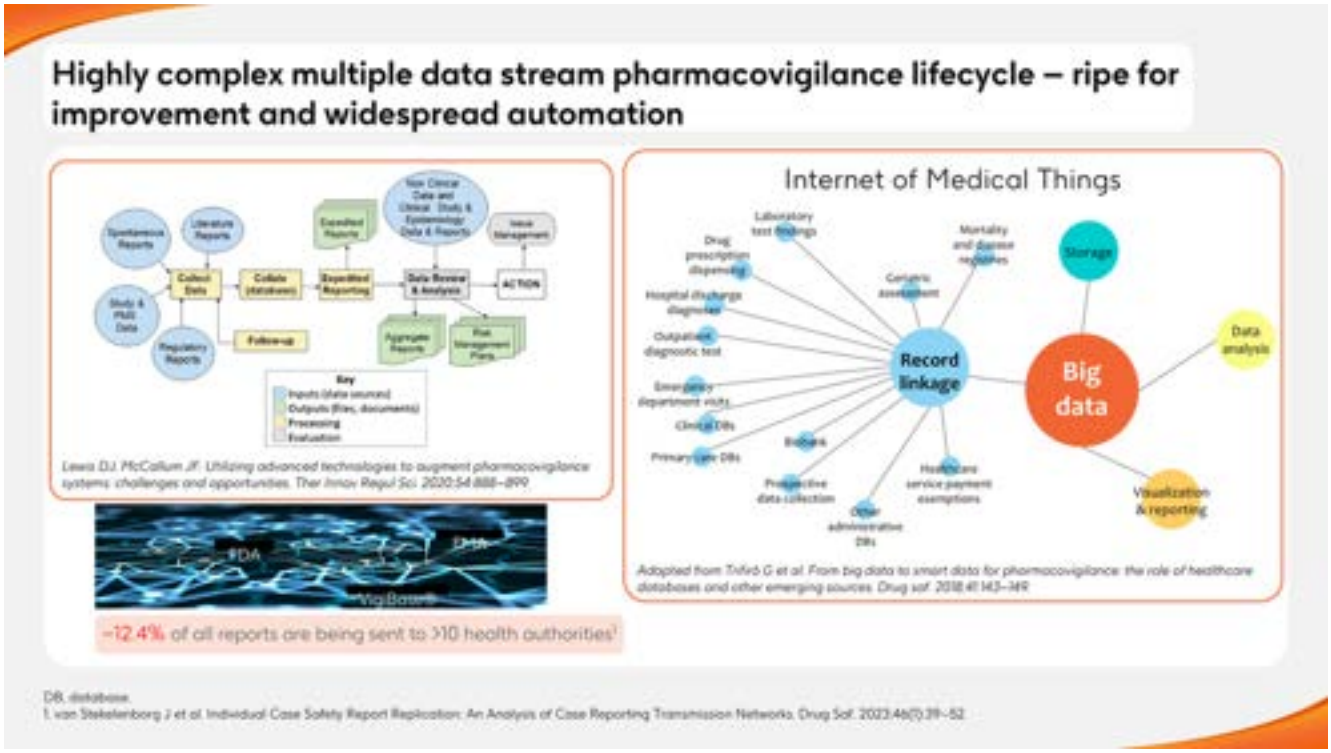
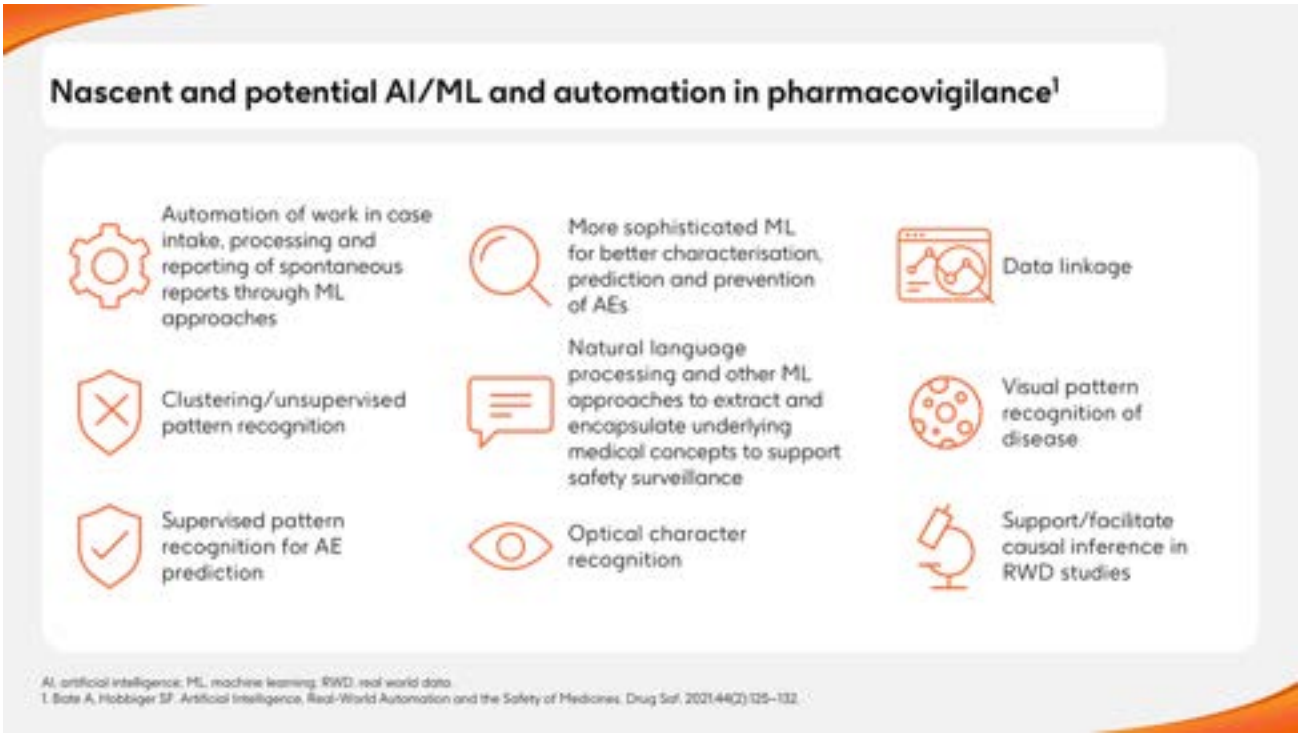


This was followed by presenting the potential of AI/ML in PV:



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Good machine learning practice - a systematic review

- If consider criteria: 1. Large datasets, 2. The use of pretrained models when appropriate, 3. Method novelty, and 4. Reproducibility
  - Reviewers' subjective evaluation found that 42 (10%) studies were reflective of modern best practices in ML/deep learning
- Vast majority (73%) used 'off-the-shelf' methods with little to no problem-specific adaptation or domain knowledge
- Similarly, 92% trained a model 'from scratch', ie only 8% leveraged a pretrained model in some capacity, and only 18% explicitly used some kind of external information or data
- 63% percent of the studies used data that were publicly available (but this included use of social media), while 7% had code that was publicly accessible at some point in time
- Of note: 10% of studies reported no explicit sample size at all

- Ref Kompa B et al. 2022 Artificial Intelligence Based on Machine Learning in Pharmacovigilance: A Scoping Review. Drug Safety. 45 (5). 477-491

The Potential Benefits Of Implementing Intelligent Automation Technologies In PV

From: TransCelerate's Intelligent Automation Opportunities in Pharmacovigilance

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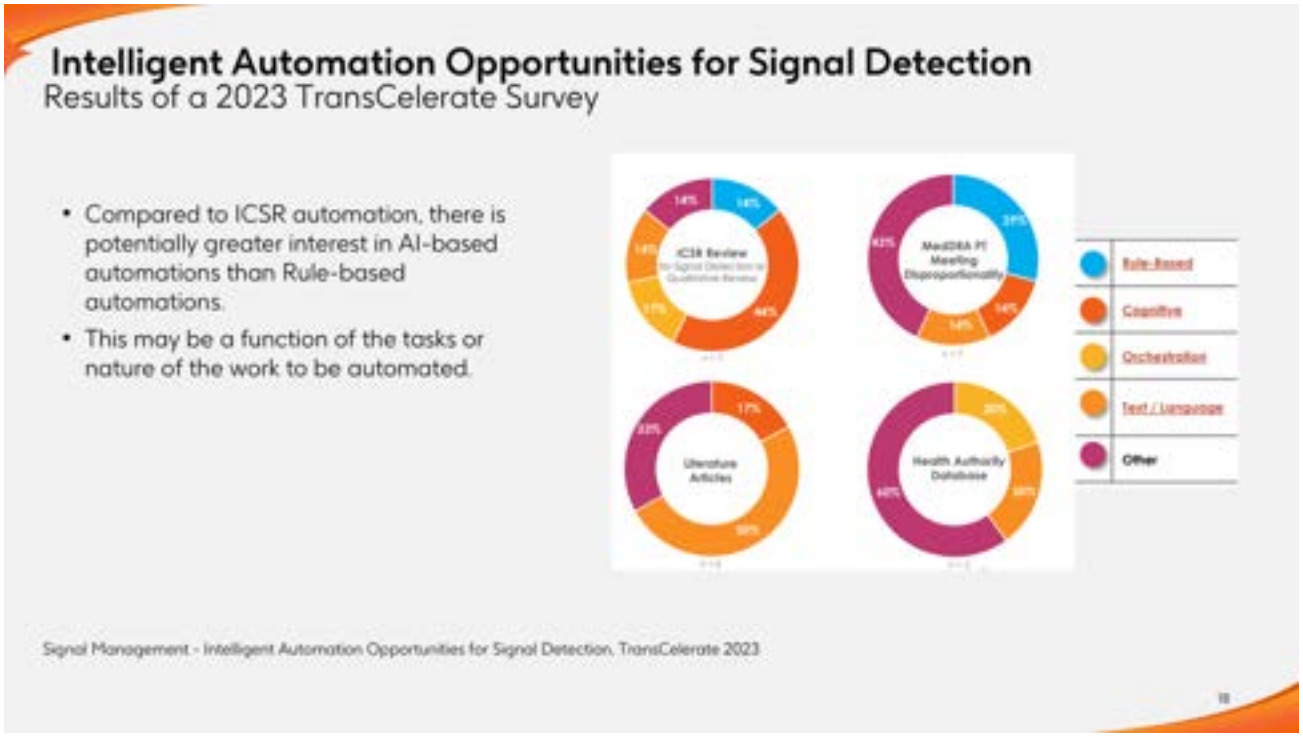
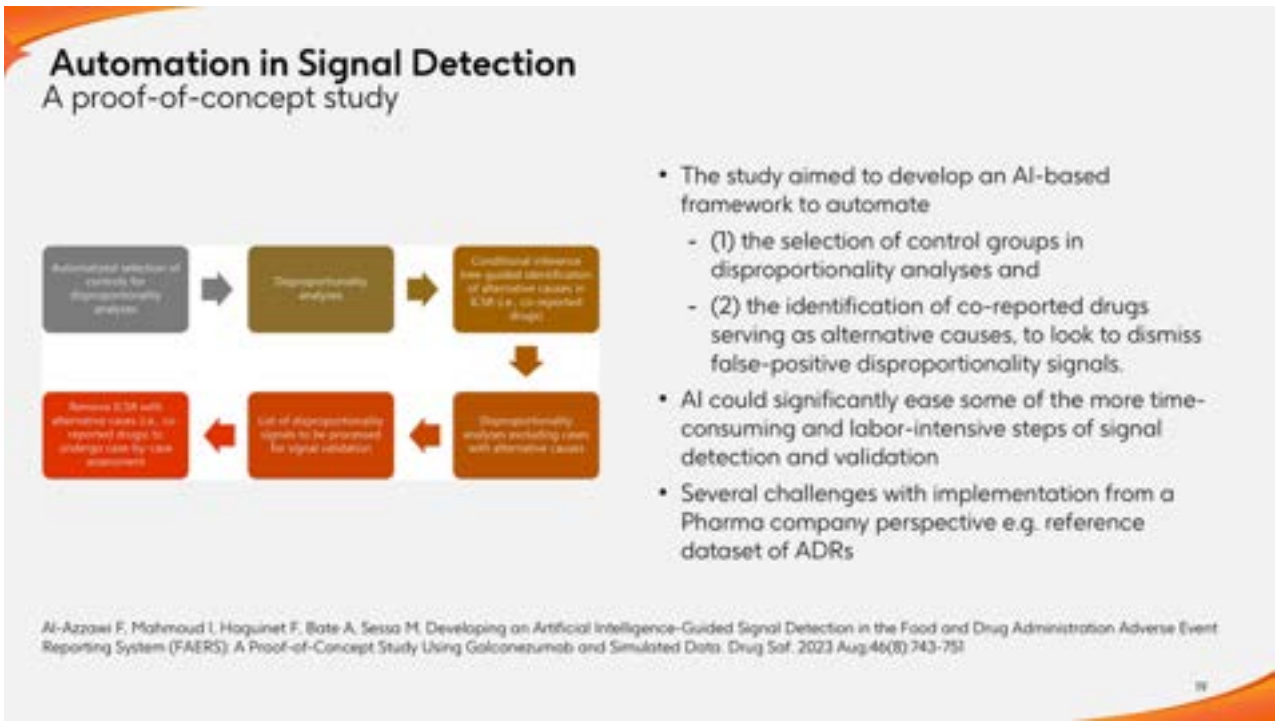
Andrew made it clear that intelligent automation opportunities for Signal Detection have an important role in the PV System:





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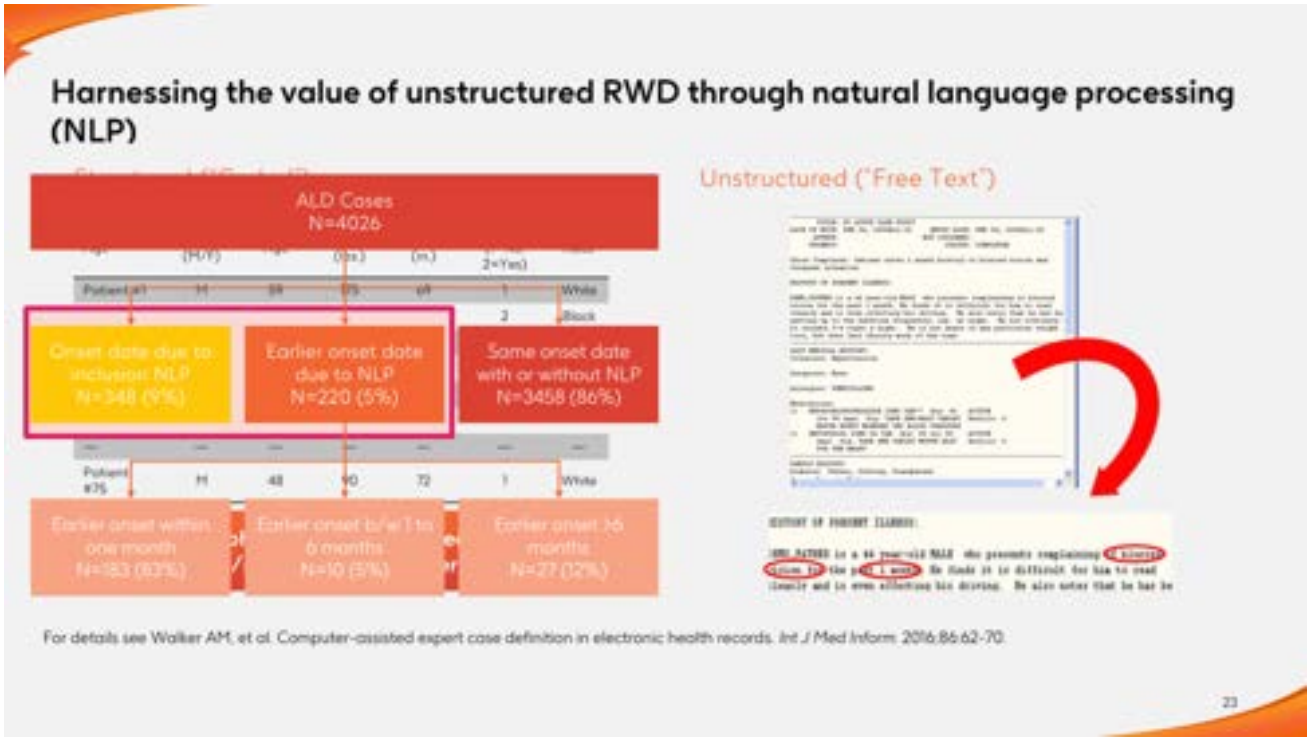
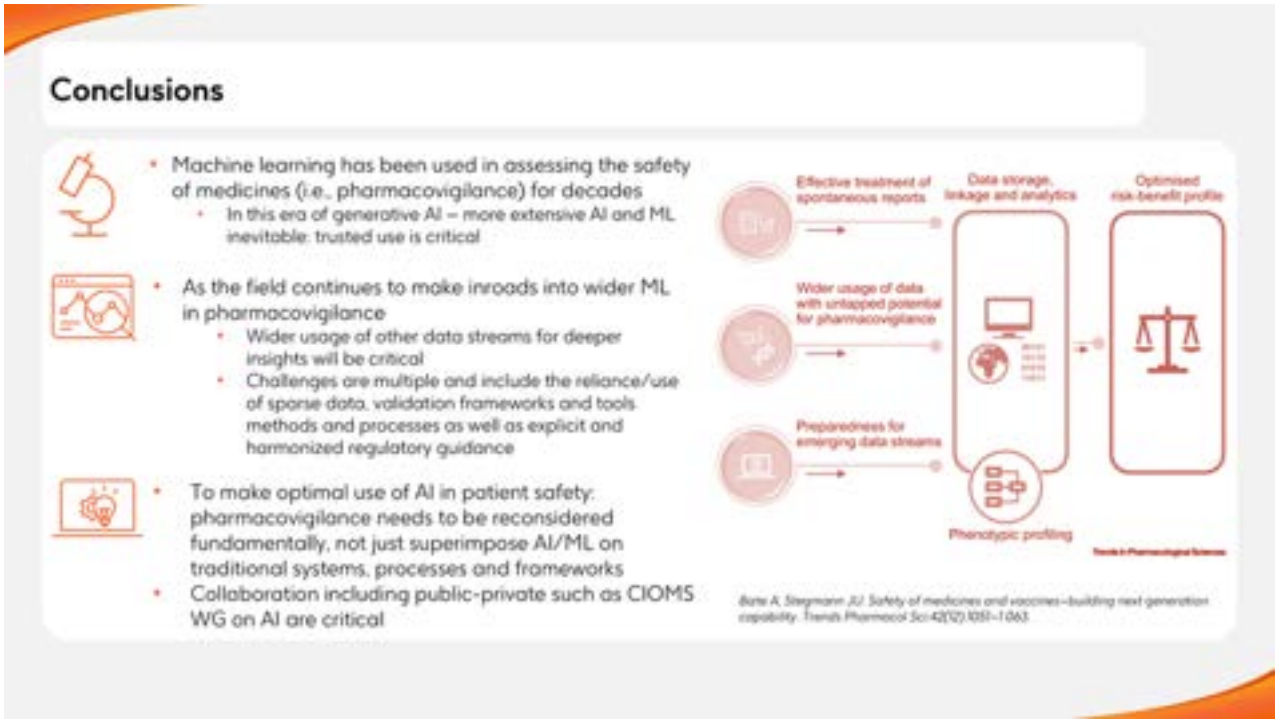
His presentation was complemented by references to the Real World Data complex:



He concluded and pointed it out also in the discussion after his presentation:



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Author: **Birka Lehmann**, MD PhD, GFMD, IFAPP ECWG (Education and Certification Working Group) Chair, Senior Expert Drug Regulatory Affairs

Free Webinars in early 2025

23 January 2025 | 12.00 noon to 1.00 pm CET
The European Young Persons Advisory Group Network (eYPAGnet)
Speakers:

- **Begoña Nafria Escalera** (Sant Joan de Déu/Barcelona, Spain)
- **Ségolène Gaiillard** (Hospices Civis du Lyon)

20 February 2025 | 1.00 to 2.00 pm CET
Declaration of Helsinki Update

- What is new for Ethics Committee?
- What is new for conducting clinical trails and everyday treatment?

Speaker: **Prof. Dominique Sprumont** (University Neuchâtel, Switzerland)

20 March 2025 | 11.00 am to 1.00 pm CET
Cardiovascular Gender Pharmacology
Speaker: **Dr Rubén Fuentes Artiles** (University Clinic/Inselspital Berne, Switzerland)

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THE FLAG

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