IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

Greetings from the President-elect

I am honoured to announce that I have been appointed as the President-elect of the prestigious IFAPP, the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine. As a member of this association, which has grown and developed over the years on the foundation of history and trust, I deeply feel the weight of responsibility for its future operations, while also being filled with hope and a sense of mission for the future.

Pharmaceutical Medicine bears an extremely important social responsibility that spans a wide range of fields, from drug research and development to post-marketing safety management and the advancement of global healthcare. In recent years, the environment surrounding us has become more complex and diverse than ever before due to rapid technological innovations such as artificial intelligence (AI) and digital transformation, globalisation, changes in the regulatory environment such as the ICH GCP revision, and the COVID-19 pandemic. As a result, the challenges facing Pharmaceutical Medicine have become even more serious.

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Firstly, there are challenges related to the development of innovative medicines and access to treatment. While cutting-edge medical technologies such as molecular targeted drugs, cell therapy, and gene therapy are making remarkable progress, the challenge of how to deliver them to patients quickly and safely remains a major issue. ICH GCP is undergoing fundamental changes to respond to the emergence of new global technologies and challenges. In this context, a multifaceted approach is required, including new clinical trial designs such as decentralised trials and umbrella trials, streamlining clinical trial procedures, utilising real-world data, and ethical considerations in the expansion of indications and clinical application of new technologies. In particular, it is an urgent task to engage in meaningful dialogue with society, as exemplified by the participation of patients and local communities, and to maximise the value of medicines.

Secondly, there are challenges related to the stable supply of medicines and the maintenance and enhancement of social trust in their safety and efficacy. In recent years, it has become essential to implement post-marketing safety measures based on risk management plans and to take swift action based on feedback from the medical field. A scientific and socially responsible approach is required, including the use of data science and AI for predicting side effects, strengthening communication with healthcare professionals and patients, and ensuring transparent information disclosure.

Thirdly, global collaboration and regulatory harmonisation are becoming increasingly important. With the spread of emerging infectious diseases and the multinationalisation of the pharmaceutical supply chain, cooperation with international regulatory authorities, industry, and academia is essential. In order to deliver innovation to the world, it is necessary to strengthen cross-border initiatives such as international joint clinical trials and global data sharing.

In order to address these challenges, I believe that IFAPP must engage in dialogue with national member associations in each country and explore paths that are attractive to all members. IFAPP has contributed to continuous education opportunities and capacity building for experts in the field of Pharmaceutical Medicine, as represented by the IFAPP Fellowship programme. In addition, we have held webinars on a wide range of important topics, mainly through our Education and Certification Working Group. Going forward, we will bring together the expertise of diverse experts, expand dialogue with patients and public, and further strengthen collaboration between industry, government, and academia. We will expand opportunities for members to freely discuss and share the latest knowledge, and actively promote the development of young talent, mainly through our Young Professional Working Group.

Next, we will promote opportunities for learning and dialogue among national member associations on topics such as the current status and challenges of utilising new technologies such as digital health, AI, and real-world data in Pharmaceutical Medicines and development and safety monitoring activities. We believe that by actively disseminating information on research and initiatives undertaken in our journal, IFAPP TODAY, and in research papers, we will be able to realise innovation in pharmaceutical development and risk management that transcends traditional frameworks. The Communication Working Group is already composed of diverse members and is very active. We will work with them to promote the dissemination of interesting information.

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Furthermore, we will promote collaboration with key stakeholders in the field of Pharmaceutical Medicine. IFAPP has already signed a cooperation agreement with the World Medical Association (WMA) and has collaborated with the Council for International Organizations of Medical Sciences (CIOMS) on various activities. I have also collaborated with CIOMS as a member of its working group on the development of 'International guidelines on good governance practice for research institutions.'

We have already begun discussions with other academic societies that share our vision for revitalising the field of Pharmaceutical Medicine and promoting international coordination, centred on the External Affairs Working Group. We will also focus on building an international network and aim to serve as a bridge between national member associations in each country.

Similarly, with regard to ethics and social co-creation that support Pharmaceutical Medicine, we will carry out activities that emphasise governance, ethical frameworks for Pharmaceutical Medicine, and international regulatory coordination and compliance, centred in the Ethics Working Group. In the 2024 revision of the Declaration of Helsinki, we participated in regional conferences held in countries around the world and published scientific papers during the revision process, which enabled us to collaborate well with the WMA. In addition, we will strengthen various initiatives to ensure transparency and reliability in research and development by always keeping in mind the perspective of patients and engaging in dialogue with them, as they are clearly identified as partners in co-creation in the ICH GCP and the Declaration of Helsinki.

The ICPM 2025, held in April 2025, was a great success, thanks to the efforts of the Dutch Association for Pharmaceutical Medicine (NVFG), the steering committee, and the scientific committee, which provided many opportunities to learn from leading experts in various fields. We are considering holding the next ICPM in Japan for the first time since 2018. The Asian region is characterised by diverse cultural backgrounds and regional communities, and we hope that the next conference will provide a good opportunity to discuss from various perspectives how to promote community engagement in the field of Pharmaceutical Medicine in an inclusive and effective manner.

Finally, I would like to express my sincere hope that you will continue to support us as partners in building the future, believing in the creativity and passion of each and every member.

Author: Kotone Matsuyama, President-elect, IFAPP
Board Certified Member of JAPhMed (The Japanese Association of Pharmaceutical Medicine) Director, Center for Clinical Research and Development, National Center for Child Health and Development

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MEAPP Highlights

Part 1: MEAPP at Africa Health ExCon 2025: Strengthening Clinical Trials Capacity in Africa

As part of its ongoing commitment to strengthening clinical research systems across the Middle East and Africa, the Middle East Association of Pharmaceutical Professionals (MEAPP) was honoured to deliver a three-day workshop titled "Strengthening Clinical Trials Capacity in Africa" during the Africa Health ExCon 2025, the continent's premier annual healthcare platform, which took place in Cairo, Egypt, from 25 to 27 June 2025.

Held under the auspices of H.E. President Abdel Fattah El-Sisi, President of Egypt, and endorsed by the Egyptian Authority for Unified Procurement (UPA), this distinguished event was co-hosted by Africa CDC (Centres for Disease Control and Prevention) in collaboration with AUDA-NEPAD (African Union Development Agency – New Partnership for Africa's Development). It brought together global healthcare leaders, policymakers, and professionals to foster innovation, enhance collaboration, and promote trade across the healthcare sector.

The workshop was organised through a generous invitation from the Society on Liver Disease in Africa (SOLDA) and proudly delivered in collaboration with MEAPP's longstanding academic partner, King's College London.

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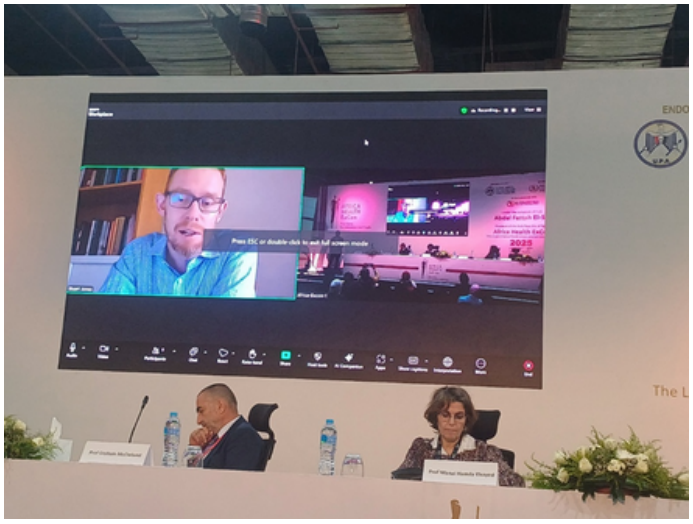
Over the three days, the workshop brought together researchers, healthcare professionals, academics, and regulators in a highly interactive hybrid setting, with participants joining both in person and virtually. The content of the workshop reflected MEAPP's commitment to practical, applicable learning. The workshop commenced with an opening welcome speech by Dr Manal Hamdy El-Sayed, Professor of Pediatrics and President of SOLDA, who set the stage by outlining SOLDA's mission and key activities. She also highlighted the challenges facing the establishment of clinical trials for Hepatitis B Virus (HBV) infection in the WHO Africa Region, including gaps in infrastructure, awareness, and regulatory capacity. This was followed by an overview of King's College London's role in capacity-building initiatives across the continent, delivered by Professor Stuart Jones, Director of the Centre for Pharmaceutical Medicine Research (CPMR) at King's College London. His remarks underscored the commitments and importance of sustainable academic partnerships in supporting the region's research ecosystem.

Prof. Manal Hamdy El-Sayed delivering the opening speech on Day 1



Prof. Stuart Jones sharing insights into King's College London's capacity-building initiatives across Africa during his virtual talk on Day 1

Next, Dr Assem El-Baghdady, Senior Lecturer in Pharmaceutical Medicine at King's College London and President of MEAPP, introduced participants to Pharmaceutical Medicine, a discipline still relatively unfamiliar in many parts of Africa and the Middle East, yet increasingly vital for the development of modern therapeutics. He highlighted the importance of building local scientific capacity, emphasising that having well-equipped scientists on the ground is essential for the next pandemic preparedness and for enabling countries to develop and access their own home-grown medicines and vaccines, rather than relying solely on external sources.

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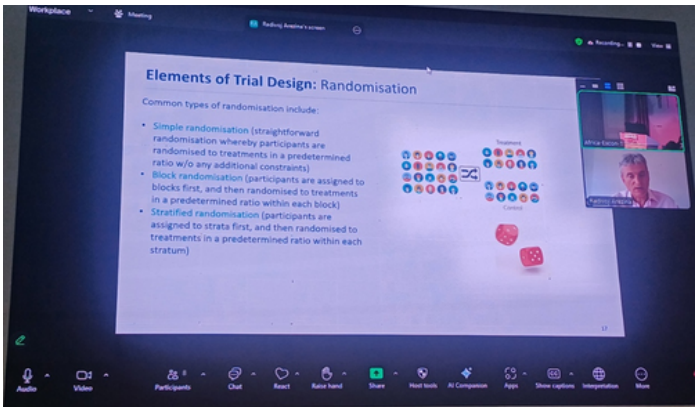
Dr Assem El-Baghdady introducing Pharmaceutical Medicine to the audience on Day 1

This was followed by Dr. Sahar Ebrahim, Head of Clinical Operations for Africa and the Middle East at IQVIA, who provided an insightful exploration of the evolving clinical trials landscape across the continent, emphasising both its tremendous potential and the challenges that must be addressed to strengthen research capacity and impact.

Exploring Africa's clinical trial potential: Dr Sahar Ibrahim's presentation on Day 1

From there, participants explored the fundamentals of clinical trials, guided by Dr. Radivoj Arezina, Visiting Senior Lecturer in Pharmaceutical Medicine at King's College London. The session covered key stages in the clinical trial process, including study design, feasibility assessment, protocol development, participant recruitment, and public engagement, providing participants with a comprehensive understanding of early-phase trial planning.



Dr Radivoj Arezina presenting on the fundamentals of clinical trials via a live online session

Day 1 concluded with an interactive activity on the Informed Consent Form (ICF), during which participants were challenged to identify multiple ethical breaches embedded in a mock scenario. The exercise sparked lively discussion and reinforced the importance of ethical rigor and participant protection in clinical research.

Day 2 focused on the ethical, legal, and regulatory frameworks of clinical research, presented by Prof. Graham McLelland, Professor of Pharmaceutical Medicine at King's College London. The session covered key areas including moral and legal responsibilities, Good Clinical Practice (GCP), regulatory guidance, contracts, and the role of ethics committees. Participants gained a clear understanding of how studies are approved, governed, and monitored, emphasising the importance of protecting participants and ensuring research integrity.

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Prof. Graham McLelland speaking on ethics and regulatory frameworks of clinical research on Day 2

One of the highlights of Day 2 was an engaging, hands-on roleplay exercise that simulated a real-world audit and inspection scenario. The speakers took on the roles of auditor and investigator, presenting situations where the audience was challenged to identify findings and propose appropriate Corrective and Preventive Actions (CAPA). This allowed participants to actively explore common challenges, regulatory expectations, and communication strategies in a high stakes setting, encouraging both critical thinking and collaborative problem-solving.

Day 3 addressed the foundations of medical statistics and the critical role of data handling, led by Dr Mohamed Taha, Biostatistics Consultant and Head of Dataclin CRO. The workshop concluded with a session on confidentiality, data security, and Good Documentation Practice (GDP), crucial pillars in protecting participant privacy, maintaining compliance, and ensuring the credibility of clinical research findings.

Insightful contributions from Dr Mohamed Taha on Day 3, highlighting the foundations of medical statistics and the vital role of the biostatistician throughout the clinical trial life cycle

Throughout the event, MEAPP was inspired by the active engagement and enthusiasm of participants. Their insightful contributions and commitment to advancing clinical research reaffirmed MEAPP's confidence in Africa's capacity to lead in conducting ethical, impactful, and locally relevant clinical trials.

As the workshop came to a close, it was clear that, while the sessions had ended, the momentum had only just begun. MEAPP remains committed to supporting the growth of a well-trained, well-connected clinical research workforce that drives innovation while upholding the rights and well-being of research participants. Through continued collaboration with regional and international partners, MEAPP also seeks to address the persistent inequality in access to high-quality Pharmaceutical Medicine education, which directly impacts the equitable development and availability of medicines. By bridging this educational gap, MEAPP aims to empower local professionals, strengthen health systems, and ultimately improve access to safe and effective treatments across underserved regions.

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MEAPP Team; Dr Assem El-Baghdady and Dr Yasmin Nagaty during the event

Group picture of some of the in-person attendees with the speakers

Part 2: Driving Forward Transnational Education: MEAPP Leads Second Milestone of Capacity-Building Programme for Medicine Development in Egypt

In June 2025, the Middle East Association of Pharmaceutical Medicine Professionals (MEAPP®), in partnership with King's College London (KCL) and Future University in Egypt (FUE), successfully completed the second milestone of their one-year transnational education project: "A Capacity Building Programme for Enhancing Clinical Research and Medicine Development in Egypt."

This phase featured the delivery of the Drug Development Statistics and Data Management module, attended by 49 professionals from academia, regulatory bodies, contract research organisations (CROs), and hospitals. The module provided advanced training in statistical principles and data handling practices essential for high-quality clinical research.

The sessions were delivered by expert faculty from King's College London, who joined both in person and virtually. Participants engaged in group coursework activities, promoting peer collaboration and problem-solving skills. The module concluded with a final multiple-choice exam, where the overall success rate was notably high, reflecting the participants' strong engagement and knowledge uptake.

This milestone marks a significant step in MEAPP's and KCL's shared mission to build capacity in Egypt's clinical research ecosystem. The initiative was made possible through a Transnational Education (TNE) Exploratory Grant, awarded by the British Council's Going Global Partnerships programme, in an effort to foster collaboration between the UK and international higher education institutions to build more equitable, globally connected education systems and strengthen capacity in higher education, science, and Technical and Vocational Education and Training (TVET).

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The final phase of the programme will take place in September 2025, focusing on Health Technology Assessment and Pharmacoeconomics, a critical area for strengthening evidence-based decision-making and resource allocation in healthcare.

As the programme progresses toward completion, MEAPP, KCL, and FUE remain committed to empowering Egypt's healthcare and scientific professionals with the expertise needed to lead in clinical research, pharmaceutical innovation, and medicine development.

Author: Yasmin Nagaty, Regional Manager | The Middle East Association of Pharmaceutical Medicine Professionals CIO (MEAPP), Visiting Lecturer, Institute of Pharmaceutical Science, King's College London

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Implementing Artificial Intelligence in Pharmacovigilance - Best Practices from CIOMS

Artificial intelligence (AI) is a rapidly evolving advanced technologies area and AI systems have been widely used already in various areas within (and outside) of Pharmaceutical Medicine. Looking at pharmacovigilance (PV), as one of the Pharmaceutical Medicine disciplines, the possible support by AI systems in daily business ranges from e.g. case intake with data extraction and automatic database entries, over quick translation into multiple languages, AI-supported literature searches/evaluation or social media listening, up to enhanced proactive signal management or even the very early prediction of safety signals. For the time being, some pharma companies have implemented AI into almost every PV process already whereas other companies are much more hesitant, somehow unsure on how to start into these new technologies or far away from having their processes ready for digitalisation, automation or AI.

Regardless of the discussion of where AI is always useful/needed or whether its added value might be overestimated to some extent in particular processes, AI is going to fundamentally reshape the PV business, and therefore clear guidance is needed for the users at pharmaceutical companies, biotech enterprises or academic research institutions.
How can AI be used in a highly regulated field like PV in a reliable/trustworthy manner?
What is important to consider while applying such AI systems? How can reliable results be achieved with such learning (and somehow explainable) systems? What about validation? And how can data privacy be ensured?

With the intention to support users and developers of AI systems in pharmacovigilance in these and other aspects of AI in PV, the Working Group XIV of the Council for International Organizations of Medical Sciences (CIOMS), consisting of experts from pharmaceutical companies, academia, regulatory agencies, and representatives from international organisations, developed a (draft) report on "**Artificial intelligence in pharmacovigilance**".

This draft document, published on 01 May 2025, aims to propose a general framework of globally harmonised principles and good practices for developing and using AI in PV, i.e. to provide practical guidance to PV professionals with regard to implementing AI into PV and to applying artificial intelligence in a reliable manner, considering that this new technology could pose a risk to patients and to public health.

For its global consensus, the group has taken into consideration a number of already existing general AI principles from different regions and countries, such as the USA, UK, Europe, Singapore and Australia (picture 1).

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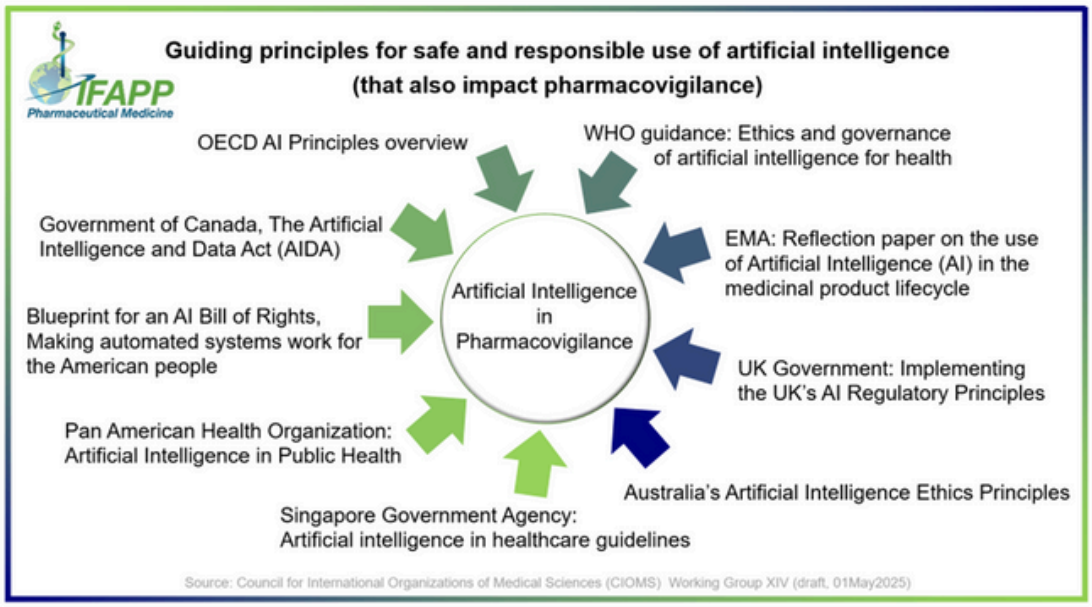
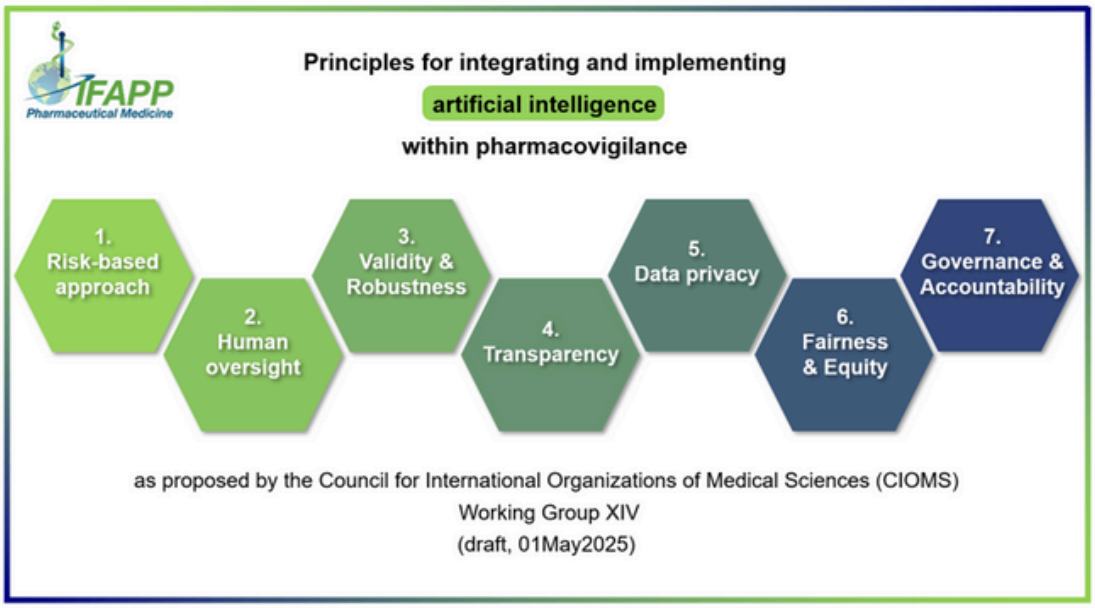


Picture 1

These general principles and recommendations do not necessarily address PV, as they rather broadly cover how to make the best use of AI while mitigating its risk as far as possible. However, due to their general nature, they certainly have influence on PV approaches as well. Hence, the CIOMS Working Group thoroughly analysed these documents and transferred them into recommendations specific for PV.

These AI principles for PV have been categorised under seven headings - covering risk-based approach, human oversight, validity and robustness, transparency, data privacy, fairness and equity, as well as governance and accountability (picture 2) - and provide key points to consider for each of these guiding principles.



Picture 2

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The risk-based approach, for example, demands to take into account the potential inaccuracies and variability of AI algorithms, including the corresponding impacts on the safety and well-being of individuals and society for tailoring the required (human) oversight to the level of risk. In order to ensure validity and robustness, PV stakeholders must learn to critically appraise proposed AI solutions, and performance evaluation must demonstrate acceptable and robust results for intended use under realistic conditions. During an AI model development, training sets must avoid propagating or amplifying harmful explicit biases underserving certain subpopulations, discrimination and inaccurate results. A robust governance structure with clear accountability is considered crucial as well.

The report further contains a number of use cases (e.g. related to case processing, causality assessments or signal detection) so that the link to daily business becomes obvious, underlining that the CIOMS report does not only contain theoretical considerations but intends to be a guide for real-life business.

The CIOMS Working Group is now in the process of reviewing the comments from the public consultation phase, and a final report can probably be awaited in early 2026.

Author: Monika Boos, M.D., Ph.D., LL.M.
on behalf of the IFAPP Pharmacovigilance Group

Swiss Annual Meeting Announcement

Everything you always wanted to know about the

Race against Antimicrobial Resistance

in one day.

Join the meeting on 25th November 2025, in Zurich, Switzerland!

Registration is open for the 30th Swiss Annual Meeting, jointly organised by the Swiss Society of Pharmaceutical Medicine, the European Center of Pharmaceutical Medicine and the Swiss Round Table on Antibiotics. Programme and registration: https://www.annual-meeting.ch/programme

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From Bench to Business: Planning for Success in Early-Stage Biotech

Introduction

The transition from preclinical research to early-phase clinical trials remains a critical step in drug development. Here we outline strategic actions for emerging biotechnology start-ups to de-risk this translational "chasm" and provide a structured approach to indication selection that aligns with regulatory expectations from the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Through deliberate end-game planning, robust operational frameworks, and evidence-driven indication prioritisation, we propose a roadmap to enhance research and development (R&D) efficiency, meet regulatory requirements, and improve commercial appeal.

Pharmaceutical innovation is often hindered by a perilous stage when projects progress from preclinical proof-of-concept to human trials. This transition, referred to here as the translational chasm, is a phase at which many promising candidates falter due to insufficient clinical planning, incomplete operational infrastructure, inadequate indication targeting, or misalignment with regulatory standards.

Indication selection is a cornerstone of translational success

Selecting the right clinical indication is a strategic imperative that underpins both the R&D success and the overall translational feasibility of biotechnology projects. Far beyond scientific exercise, indication selection connects the mechanistic promise of a novel therapy with clearly defined medical needs, regulatory expectations, and commercial opportunity.

The process should begin with a comprehensive review of available data, including insights into the drug's mechanism of action, target biology, pharmacological profile, and preclinical evidence. This includes evaluating data from in-vitro studies, animal models, biomarker research, and early toxicology findings. Any evidentiary gaps should be identified through a systematic gap analysis, guiding further research efforts.

In parallel, the clinical relevance of the drug target should be validated through a robust understanding of its role in disease pathophysiology. This involves identifying supportive biomarkers and diagnostic tools that can facilitate patient selection and outcome measurement in clinical trials.

A systematic and reproducible literature search strategy is essential in order to identify the unmet medical needs, epidemiological trends, and the competitive development landscape. Applying rigorous inclusion and exclusion filters helps refine the list of possible indications.

Filtering potential indications should then be approached through a multi-disciplinary approach. Priority should be given to those that demonstrate a substantial unmet medical need, alignment with regulatory incentives (such as orphan designation or accelerated review), deficiencies in current clinical guidelines, and a favourable market outlook. The indication should also resonate with the broader development strategy, whether aiming for licensing deals, initial public offerings (IPO), or commercialisation.

Equally important is stakeholder engagement. Input from healthcare professionals, patients, caregivers, and key opinion leaders (KOLs) is indispensable for understanding real-world disease burden and therapeutic gaps. Structured interviews, surveys, and advisory boards help quantify the added value of a new therapy and shape clinical endpoints that matter to both regulators and patients.

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The landscape is not static. Competitor activity must be continuously tracked through resources like ClinicalTrials.gov and commercial intelligence platforms, ensuring the chosen indication remains both viable and differentiated in a rapidly evolving field.

Strategic planning: Begin with the end in mind

All findings should be consolidated into a structured indication selection dossier. This document should clearly outline the methodology, rationale, prioritised indications, and stakeholder insights, serving as a critical reference point for internal decision-making and external engagement with regulators and investors.

Yet, defining the right indication is only the beginning. To translate that choice into a meaningful and executable development plan, the next essential step is to develop a Target Product Profile (TPP). The TPP acts as a strategic blueprint for development, defining the intended use, target population, clinical benefits, and key differentiators of the product. This document is a living document that ultimately will develop into your product label at the time of market access. It aligns all stakeholders, i.e., clinical, regulatory, and commercial, around a common vision of the product's final form and value proposition.

The FDA strongly encourages the use of TPPs to facilitate structured drug development and regulatory dialogue. As outlined in the FDA's guidance document, "Target Product Profile – A Strategic Development Process Tool", the TPP can help sponsors and regulatory agencies align on expectations early in development, thereby increasing efficiency and reducing the risk of costly misalignments later in the programme.

Value Inflection: From Plan to Execution

In summary, indication selection must be anchored in both scientific rigour and strategic foresight. When followed by the systematic development of a TPP, this approach lays a strong foundation for clinical programme planning, regulatory alignment, and eventual market success.

Effective execution transforms strategic intent into tangible outcomes: successful regulatory submissions, investor confidence, and a compelling commercial proposition. Translational success relies on bridging scientific potential to patient benefit through robust, evidence-based planning and execution.

Author: PD Dr Ghazaleh Gouya-Lechner, CEO Gouya Insights, Board member IFAPP and the Austrian National Member Association (GPMed)

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Introducing PFMD to the IFAPP Community

Patient Focused Medicines Development (PFMD) is a global, multi-stakeholder collaborative and non-competitive coalition committed to making patient engagement (PE) the norm in the healthcare ecosystem. Co-led with patients, PFMD provides a platform for the global PE community to come together, discuss experiences and challenges, and co-create frameworks, tools, and systems that ensure patient voices are a central element at every stage of healthcare development. With over 2,000 collaborating organisations worldwide, PFMD offers practical solutions like the PE Quality Guidance, a Fair Market Value calculator, and legal templates, all designed to drive the widespread adoption of meaningful patient engagement. Through a strong digital network, Synapse, which maps over 900 patient engagement initiatives, and gatherings like the Patient Engagement Open Forum, PFMD fosters a transparent, global community that empowers collaboration across sectors.

Looking ahead, PFMD and IFAPP envision a strong partnership where IFAPP members can actively participate in the Patient Engagement (PE) community. By joining the conversation, members will gain access to valuable touchpoints, resources, and tools that can advance patient engagement practices across their work. Together, we aim to support the integration of patient-centred approaches in regulatory, health technology assessment (HTA), and beyond, making PE a foundational element in global healthcare systems.

Author: Eleonora Barile, Program Manager, The Synergist

PFMD.org
Made WITH Patients

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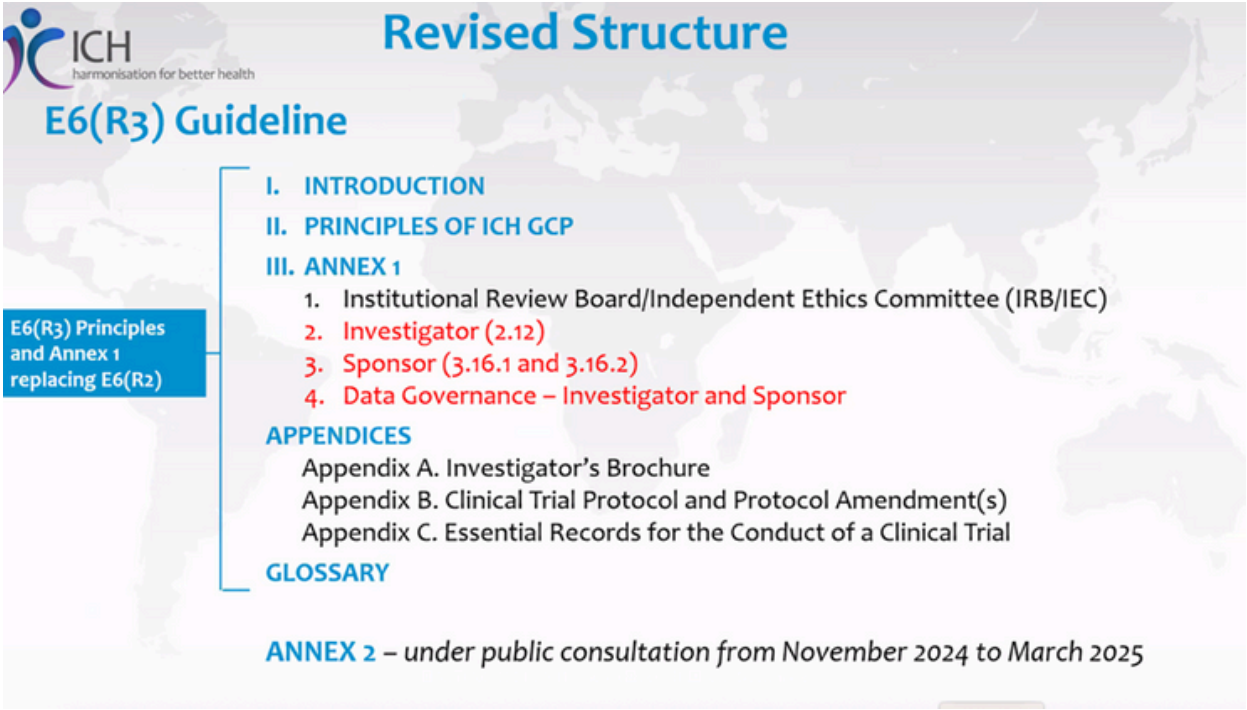
Summary of the Webinar of 30 June 2025

ICH–GCP revision 3

The speakers were:

- Gabriele Schwarz, BfArM's GCP Strategy Expert and representative of the EC/EU in the ICH E6(R3) Expert Working Group, and
- Rebecca Stanbrook, EFPIA Topic lead for ICH E6(R3) Expert Working Group.

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



In the two-hour expert training session, the attendees received a comprehensive update on the major revisions to ICH E6(R3):

The revision marks a significant rewrite of the guideline, reflecting extensive stakeholder engagement and a commitment to transparency. While retaining its scope - interventional clinical trials of medicinal products for human use - the revision introduces a flexible framework intended to remain relevant across trial types and as technologies evolve. A key feature is the use of two annexes to support the practical application of its 11 principles, promoting a risk-based, fit-for-purpose approach to trial conduct.

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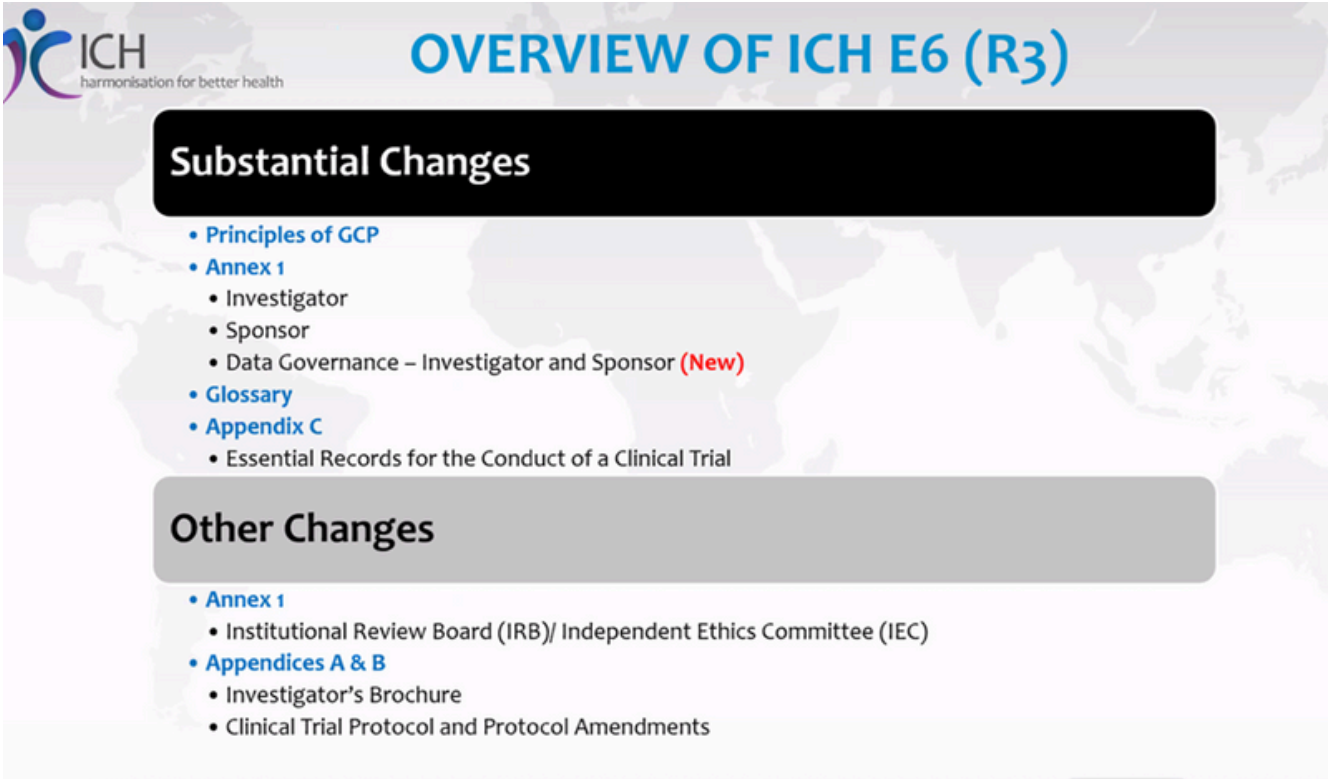
The session explored core concepts such as quality-by-design, operational feasibility, and the importance of avoiding unnecessary complexity or burden on both trial participants and investigators. Emphasis was placed on proportionality and risk-based quality management.

New definitions and expanded expectations for investigators were also discussed, including updated provisions on informed consent, re-consent, and assent of minors, as well as qualifications and training of investigators and persons assisting investigators, oversight of service providers and major changes to safety management and reporting. Investigator responsibilities related to computerised systems, data handling, and investigational product management were also covered.

Key changes in relation to sponsor responsibilities have been presented, including the quality-by-design approach to trial design, agreements, oversight of service providers and sites, and robust data and investigational product management strategies.

The importance of data governance across the entire data lifecycle was underscored, with particular attention to computerised systems covering validation, security, training, technical support, and system failure procedures.

Finally, the session addressed essential records, highlighting their importance in demonstrating compliance and data integrity.



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The overall keywords are:

- Fitness for Purpose
- Proportionality
- Encourage Thinking!

The majority of the slides originate from the ACT-EU Workshop on ICH E6(R3), held from 19-20 February 2025 in Amsterdam.
https://www.ema.europa.eu/en/events/act-eu-workshop-ich-e6-r3-principles-annex-1 including video recording.

Authors: Gabriele Schwarz, Rebecca Stanbrook and Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

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IFAPP Secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Assem el Baghdady, Varvara Baroutsou, Francesco Butti, Brigitte Franke-Bray (Editor), Anna Jurczynska, Rita Lobatto, Hasan Mahmood, Kotone Matsuyama, Yasmin Nagaty (Editor), Helio Osmo, Joanne Ramsey, and Alexandra Reis Stoffel

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