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The Global Pharmaceutical Medicine Journal



**INTERNATIONAL FEDERATION OF  
ASSOCIATIONS OF  
PHARMACEUTICAL PHYSICIANS  
AND PHARMACEUTICAL MEDICINE**

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Pharmaceutical Medicine



## Celebration of MedSafetyWeek: Preventing Side Effects



The Uppsala Monitoring Centre celebrates every year the MedSafetyWeek, and in collaboration with medicines regulatory authorities and national pharmacovigilance centres across the world has the aim to raise awareness of pharmacovigilance systems among the public and promote the reporting of suspected Adverse Drug Reactions. This year the campaign will be celebrated from 4 to 10 November 2024 and will focus on preventing side effects (Uppsala, 2024).

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According to WHO side effects or adverse drug reactions are any harmful, unintended reactions to medicines that occur at doses normally used for treatment. In the modern healthcare environment, with new emerging complex therapeutics and in parallel an aging population with a plethora of comorbidities and polypharmacy, side effects constitute a considerable challenge as one in ten patients suffer from adverse events (WHO, 2024). According to studies adverse drug reactions (ADRs) are responsible for 10% of outpatient appointments and 3.5–10% of hospital admissions and are the fifth leading cause of death in hospitalised patients, in addition to prolonging stays and generate a high economic impact (García-Abeijon, 2023). As per Global Patient Safety report 2024 published by WHO the occurrence of adverse events, resulting from unsafe care, is likely to be one of the 10 leading causes of death and disability worldwide. Recent evidence suggests that 134 million adverse events occur each year due to unsafe care in hospitals in low- and middle-income countries (LMICs), resulting in 2.6 million deaths annually (WHO, 2019).

A significant number of Adverse Drug Reactions (ADRs), potentially up to 60% in certain cases, can be avoided. These preventable ADRs can stem from a range of factors. These include prescribing the wrong drug or administering incorrect dosage, misdiagnosis of the patient's health condition, overlooking a hidden health condition (medical, genetic or allergic) that could precipitate a reaction in a patient, instances of self-medication with prescription drugs, non-compliance with medication use guidelines, and drug to drug or drug to food interactions. Furthermore, the use of counterfeit drugs, which lack active ingredients or contain inappropriate ingredients, poses a serious, even life-threatening risk (WHO, 2020). In the crucial question on how to prevent adverse effects there are two fundamental steps to adhere to: firstly, it is to correctly identify if the patient is likely to be prone to the adverse effect and modify the treatment choice accordingly, for example, via a thorough search in the patient's medical history for previous ADRs.

Moreover, susceptibility factors such as age, gender, pregnancy status, disease state, comorbidities such as renal or hepatic conditions which may alter drug metabolism, polypharmacy and ethnicity, can assist in predicting the risk of an ADR occurring (NICE, 2022). For instance, because of the risk of ACE inhibitor-induced angioedema in patients of African or Caribbean regions should be prescribed an angiotensin-II receptor blocker in favour of an angiotensin converting enzyme (ACE) inhibitor for hypertension. It's also significant to note that pharmacogenetics is beginning to pave the way for more individualised medication options by determining who is more likely to experience a specific ADR. Secondly, it is important to ensure that the treatment plan mitigates any possible side effects. Risk mitigation procedures can involve: i) providing clear instructions for use for all newly prescribed medication, ii) correctly assess and advise on the potential risk of drug–drug or food interactions, or other lifestyle choices (alcohol or smoking) interacting with medication, iii) informing the person, or their care provider, about any known ADRs when prescribing a new medication, iv) ensuring the person complies with any required monitoring of clinical or biochemical parameters as recommended in prescribing guidelines, v) use of agents in the management of specific adverse drug reactions such as coprescription of folic acid with methotrexate will reduce the incidence of adverse effects associated with folate deficiency (Coleman, 2016).

Another determinant factor for the prevention of adverse drug reactions would be the continuous monitoring and reporting of ADRs so as to have a complete and accurate safety profile of each drug. All pharmaceutical entities across the world are mandated by law to conduct clinical trials on their medicinal products before these drugs can be made publicly accessible. Such trials provide valuable insights into how effective a drug is for a specific condition and identify its potential harms.



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However, the knowledge gained from these trials has limitations as they don't necessarily provide extrapolative information for broader population groups not represented in the trials, such as different ages, genders, health statuses, and ethnicities. Safety vigilance for many drugs, especially those of a complicated nature, is not limited to the manufacturing phase. Post-market surveillance, a phase that includes careful patient monitoring and further data collection, becomes vital for ensuring drug safety. This ongoing process of drug monitoring post its approval is crucial in safeguarding patients. The spontaneous reporting of suspected ADRs by health professionals allows continuous determination of the benefit–risk ratio of a given drug and is one of the best methods to generate signals regarding unexpected events and rare ADRs. Underreporting is a major limitation of spontaneous notification systems, as it is estimated that only 6–10% of all ADRs are reported. Many reasons for this high percentage of underreporting have been identified such as (1) ignorance (only serious ADRs need to be reported) in 86.2%; (2) lethargy (procrastination, lack of interest, and other excuses) in 84.6%; (3) complacency (the belief that only well tolerated drugs are allowed on the market) in 46.2%; (4) diffidence (fear of appearing ridiculous for reporting merely suspected ADRs) in 44.6%; and (5) insecurity (it is nearly impossible to determine whether or not a drug is responsible for a specific adverse reaction) in 33.8% (García-Abeijon, 2023). Nevertheless, all these factors are potentially modifiable through educational interventions and awareness campaigns.

Lastly, we must not overlook the significant potential that artificial intelligence (AI) is beginning to unravel in the last years. AI has started to impact many processes in pharmacovigilance such as case intake, processing, signal detection and analysis and, therefore, can contribute to harnessing all this large volume of health data that possibly contain side effects. Only with the correct use of AI we have the capacity to minimise the workload, complexity and budget of pharmacovigilance activities and, therefore, enable the focus on the most crucial elements of patient safety (Bate, 2023).

In conclusion, it is of critical importance that all healthcare and pharmaceutical professionals recognise the harmful impact of side effects and join the effort in preventing them to protect the healthcare systems from the burden of the financial costs and most importantly to ensure that patients derive the highest therapeutic benefit from their medications.

PS: In this context, don't miss the upcoming webinar on “AI-based post marketing monitoring” on 20th Nov (11:00 a.m. - 01:00 p.m. CET) with Andrew Bate as speaker and panellists from the Pharmacovigilance Working Group (link to be announced soon).

## References

- [#MedSafetyWeek | UMC \(who-umc.org\)](#)
- [Global patient safety report 2024 \(who.int\)](#)
- [10 facts on patient safety \(who.int\)](#)
- [Ensuring medicines work safely for everyone \(who.int\)](#)
- García-Abeijon P, Costa C, Taracido M, Herdeiro MT, Torre C, Figueiras A. Factors Associated with Underreporting of Adverse Drug Reactions by Health Care Professionals: A Systematic Review Update. *Drug Saf.* 2023 Jul;46(7):625-636. doi: 10.1007/s40264-023-01302-7. Epub 2023 Jun 6. PMID: 37277678; PMCID: PMC10279571 [safety-of-medicines--adverse-drug-reactions-jun18.pdf \(who.int\)](#)



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- Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med (Lond). 2016 Oct;16(5):481-485. doi: 10.7861/clinmedicine.16-5-481. PMID: 27697815; PMCID: PMC6297296.
- Slawomirski, L. and N. Klazinga (2022), "The economics of patient safety: From analysis to action", OECD Health Working Papers, No. 145, OECD Publishing, Paris, <https://doi.org/10.1787/761f2da8-en>.
- [Preventing ADRs | Background information | Adverse drug reactions | CKS | NICE](#)
- Andrew Bate, Jens-Ulrich Stegmann, Artificial intelligence and pharmacovigilance: What is happening, what could happen and what should happen? Health Policy and Technology, Volume 12, Issue 2, 2023, 100743, ISSN 2211-8837, <https://doi.org/10.1016/j.hlpt.2023.100743>

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## MEAPP 2nd Annual Conference: Pharmaceutical Medicine Domiciliation in the Middle East

The Middle East Association for Pharmaceutical Medicine Professionals (MEAPP) successfully hosted its second annual conference in Amman on September 25-26, 2024. Held under the esteemed patronage of HRH Prince Al Hassan bin Talal of Jordan and in partnership with Amman Arab University, the conference served as a cornerstone event for pharmaceutical professionals in the region.

In a region where the concept of Pharmaceutical Medicine is relatively new, the conference introduced the audience to this specialty, emphasising its importance and potential impact while also underscoring the urgent need to foster innovative medicine development and build the capacities of a new generation of scientists capable of driving innovative medicine development.

In his inaugural speech, Dr. Assem S. el Baghdady, President and Co-founder of MEAPP, warmly welcomed the dignitaries and audience. He emphasised the pivotal role of the rapidly evolving Pharmaceutical Medicine in shaping a future of equitable and accessible healthcare globally and the urgent need for the Middle East region to develop its own medicines at this critical juncture.



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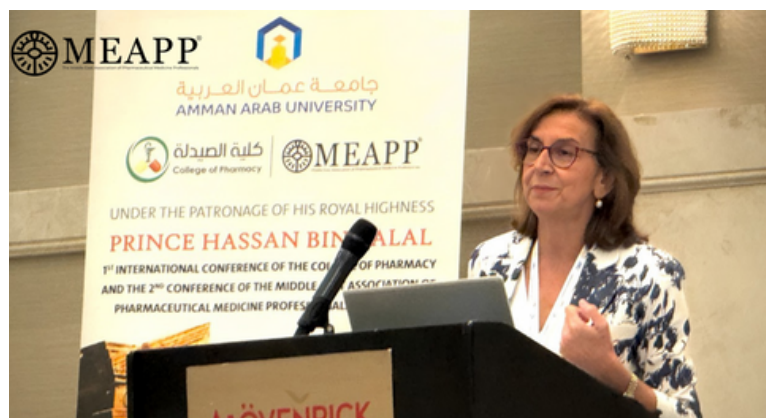


While acknowledging the region's significant manufacturing capabilities, Dr. el Baghdady stressed the lack of original innovation in new medicines. He stated that innovating medicine is no longer a luxury but a matter of national security for the region. The recent global pandemic served as a harsh reminder of this reality, highlighting the region's vulnerabilities.

With ongoing wars and conflicts in the region, as emphasised by former Jordanian Minister of Health HE Dr. Saad Jaber representing HRH Prince Al Hassan bin Talal, there is an acute need for sustainable strategies to localise the innovation of medicines in the region. This localisation is not merely about supporting local industries but ensuring swift and effective response to the region's health challenges.

The event was graced by notable attendees, including delegates from various Jordanian embassies, the World Health Organization (WHO), and Médecins Sans Frontières.

We were honoured to have Dr. Varvara (Barbara) Baroutsou, the President of the IFAPP, deliver an insightful presentation on the global role of IFAPP in promoting Pharmaceutical Medicine, connecting regional efforts to a broader international framework.



*IFAPP President, Varvara (Barbara) Baroutsou, during her presentation in the conference*



*Dean of the College of Pharmacy at Amman Arab University, Prof. Rana Abu Huwajj, presenting a certificate of appreciation to Dr. Varvara (Barbara) Baroutsou.*



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Speakers from prestigious institutions, including King's College London, the Faculty of Pharmaceutical Medicine (FPM), Ernst & Young (EY), the Jordan Food and Drug Administration (JFDA), the Kuwait Ministry of Health, alongside representatives from Jordanian pharmaceutical companies and both Jordanian and Egyptian Contract Research Organisations (CROs), contributed significantly, enriched the conference discussions and engaged the audience.

The two-day conference featured a comprehensive agenda that included keynote speeches, scientific sessions, poster presentations, and panel discussions. Attendees explored cutting-edge research, engaged in thought-provoking discussions on critical issues, and participated in hands-on workshops on regulatory affairs and best Pharmacovigilance practices. We awarded prizes to the top three poster presenters and introduced a new award for the 'Youngest Researcher,' which was granted to a high school student from Egypt. This recognition showcased the promising future of scientific talent in the region.

The feedback from attendees was overwhelmingly positive, reflecting the success and impact of the conference. Participants praised the quality of the sessions and the depth of discussions, which were both challenging and enlightening. A strong recommendation emerged for an enhanced collaboration among all stakeholders, including academia, regulatory bodies, the pharmaceutical industry, and CROs. Such collaboration is essential to advance clinical research and innovation in the region.

Another significant recommendation was the regulatory alliance initiative aimed at harmonising the registration processes for medicines and biologics across the Middle East. A unified regulatory framework is critical for streamlining cross-border collaborations, accelerating innovation, and improving access to medicines. This would not only support local pharmaceutical industries but also attract global investments and partnerships.



*MEAPP Team, Assem Elbaghdady & Yasmin Nagaty with Varvara (Barbara) Baroutsou, IFAPP President*



*From right to left: Mark Lighthowler (EY), Dusko Ilic (KCL), Assem Elbaghdady (MEAPP), Yasmin Nagaty (MEAPP), Varvara (Barbara) Baroutsou (IFAPP), Stuart Jones (KCL), and Timm Urschinger (EY).*

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## Review of and Update on Mpox

For the second time in little more than two years, the World Health Organization (WHO) recently declared a public health emergency of international concern (PHEIC) for an ongoing outbreak of mpox (1), a viral disease previously called “monkeypox”. The International Health Regulations of 2005 (2) define a PHEIC as “an extraordinary event ... to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response”.

Mpox is caused by an orthopoxvirus, MPXV, which was discovered in 1958 in captive monkeys (hence the misnomer). In 1970, during the final decade of the smallpox eradication campaign, the first MPXV infection was diagnosed in a human being in what is now the Democratic Republic of the Congo (DRC).

Mpox subsequently came to be seen as a relatively rare zoonotic disease with limited geographic distribution, acquired mainly through close contact with wild mammals, especially when handling “bush meat”. MPXV is endemic to forest areas of tropical central and west Africa, with clade I MPXV occurring in the Congo basin and clade II along the West African coast (3). Available data suggests that clade I MPXV carries a higher case fatality rate (CFR) than clade II.

Even though MPXV was transmissible from person to person, no sustained human-to-human transmission was noted for over 40 years. Yet from the beginning concerns were voiced that once smallpox vaccination using vaccinia (which provides cross-protection against MPXV, too) would cease, diminishing population immunity might lead to the emergence of mpox (4). Prior to 2022, very few mpox cases occurred outside the known endemic areas, imported by infected travellers or the importation of infected small mammals to the U.S.A. in 2003.



Wolfgang Preiser

A lot of unknowns remain, due to a lack of funding for research into a disease apparently not posing a threat to the global community. There was little interest in developing vaccines, antiviral drugs or developing diagnostic tools. That said, mpox benefitted from funding to prepare for the possible nefarious use of smallpox and other orthopoxviruses. Thus, research was conducted on antiviral entities and newer types of vaccines, and stockpiles were created since the early 2000s.

This foresight became enormously useful when, starting early in 2022, mpox cases appeared unexpectedly and en masse in numerous countries around the world that had never previously reported the disease. This rapidly evolving global outbreak (5) has so far caused over 99,000 laboratory-confirmed cases in 116 countries. At its peak in August 2022, over 6,000 cases were reported per week.

The sudden and dramatic spread, especially affecting among men who have sex with men, triggered the first PHEIC declaration for mpox (6). The causative agent was identified as MPXV clade IIb, closely related to previous sequences from Nigeria, where human-to-human mpox spread had been going on for several years already, receiving little attention abroad.



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Publicity campaigns led to safer behaviours and vaccination was made available (using vaccine stockpiles intended for biowarfare or bioterrorism). This quickly changed the trajectory of this almost global outbreak, and the PHEIC was declared over in May 2023. Cases do still occur in many countries, but numbers are small. Overall, the global MPXV clade IIb outbreak was characterised by a low case fatality rate (below 1%). This may be attributed to viral characteristics, patient characteristics, and/or the quality of medical care. It, however, does not mean that mpox is a negligible disease: After no cases in 2023, South Africa saw 25 diagnosed mpox patients in 2024 so far (7) of which three succumbed to the disease and several others were seriously ill but survived. Their common factor was advanced immunodeficiency, usually caused by untreated longstanding HIV infection.

Meanwhile, in Africa, MPXV clade I continues to cause sporadic cases in the Congo river basin, as it has been doing for a long time. Alarmingly, though, it is also behind an ongoing upsurge of mpox cases with its epicentre in the eastern DRC, which started in 2023 (8). The virus implicated in this outbreak has been classified as a new sub-clade, Ib, which worryingly bears the genetic imprint of prolonged circulation among human beings (9). A common mode of transmission is sexual, affecting miners and sex workers but also the wider community. This outbreak already has led to mpox cases occurring in several neighbouring countries and even on other continents.

Since the beginning of 2024, 14 countries in the WHO African region (10) have reported 32,808 suspected mpox cases with 844 suspected mpox deaths; the figures for laboratory-confirmed cases and deaths are 6,602 and 32, respectively.

This poses a tremendous challenge. The latest WHO African Region weekly bulletin (11) lists no fewer than seven emergencies for the eastern part of the DRC, from floods and a humanitarian crisis due to ongoing violent strife via cholera, measles and two strains of poliovirus, to mpox. The challenges of bringing the mpox outbreak under control before it spreads further are formidable. On the upside, not that long ago the country eventually overcame the second-largest Ebola outbreak ever recorded (12).

All three epidemiological mpox patterns overlap in Africa at present (13):

1. endemic cases from a zoonotic source, as experienced for a long time (clade Ia);
2. cases linked to the 2022 global outbreak (clade IIb); and
3. the recently recognised clade Ib MPXV with prolonged transmission chains among human beings in eastern parts of the DRC.

It is not clear why over the course of only a few years, two different virus clades took on characteristics previously not observed in decades. Is this coincidence, or does it point to a common underlying mechanism? As MPXV clade IIb has demonstrated, regarding an infectious disease as a mere local issue is risky, as it may yet emerge and spread rapidly and widely (14).

Fortunately, the mpox control effort can build on previous work done for an entirely different scenario. WHO recently prequalified (15) the Modified Vaccinia Ankara (MVA)-Bavarian Nordic vaccine (16), a non-replicating third-generation vaccine originally developed against smallpox. Prequalification by WHO (17) will hopefully facilitate access to what is arguably the most important intervention to bring the current outbreak under control.





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Several countries have made vaccine doses from their stockpiles available for use in the most affected African countries (18).

Addressing the other major shortcoming, namely the lack of accessible and affordable diagnostic testing (DRC reports far more suspected mpox cases than are laboratory-confirmed, reflecting very limited access to such testing), WHO has also called upon the in vitro diagnostics industry to submit applications for emergency use listing (19).

To avoid a scenario like during the COVID-19 pandemic, where limited supplies (e.g., masks and vaccines) were not allocated effectively and equitably across the world with priority for people at highest risk, WHO has established an access and allocation mechanism (20) for medical countermeasures (vaccines, treatments and diagnostic tests) against mpox.

It remains to be seen whether there will be sufficient political commitment and financial backing for a rapid and effective outbreak response. Like West Nile, Zika and Chikungunya, mpox has turned out as yet another “exotic” virus that, after decades of obscurity, suddenly emerges to pose a global threat. Unfortunately, significant funding for research and outbreak control tends to become available only once wealthier countries are threatened.

## References

- 1) <https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern>
- 2) <https://www.who.int/health-topics/international-health-regulations>
- 3) Djuicy DD, Sadeuh-Mba SA, Bilounga CN, Yonga MG, Tchatchueng-Mbouguia JB, Essima GD, Ezzo L, Nguidjol IME, Metomb SF, Chebo C, Agwe SM, Ankone PA, Ngonla FNN, Mossi HM, Etoundi AGM, Eyangoh SI, Kazanji M, Njouom R. Concurrent Clade I and Clade II Monkeypox Virus Circulation, Cameroon, 1979-2022. *Emerg Infect Dis*. 2024 Mar;30(3):432-443. doi: 10.3201/eid3003.230861. Epub 2024 Feb 7. PMID: 38325363; PMCID: PMC10902553
- 4) Weyer J, Blumberg LH. Monkeypox: Is the 'vacated niche' being filled? *S Afr J Infect Dis*. 2022 Dec 12;37(1):479. doi: 10.4102/sajid.v37i1.479. PMID: 36568331; PMCID: PMC9772718
- 5) [https://worldhealthorg.shinyapps.io/mpox\\_global](https://worldhealthorg.shinyapps.io/mpox_global)
- 6) <https://www.who.int/europe/news/item/23-07-2022-who-director-general-declares-the-ongoing-monkeypox-outbreak-a-public-health-event-of-international-concern>
- 7) <https://www.nicd.ac.za/mpox-updates/>
- 8) Cevik M, Tomori O, Mbala P, Scagliarini A, Petersen E, Low N, Heymann D, Shan Lee S, Blumberg L. The 2023 - 2024 multi-source mpox outbreaks of Clade I MPXV in sub-Saharan Africa: Alarm bell for Africa and the World. *Int J Infect Dis*. 2024 Sep;146:107159. doi: 10.1016/j.ijid.2024.107159. Epub 2024 Jul 1. PMID: 39028567
- 9) Vakaniaki EH, Kacita C, Kinganda-Lusamaki E, O'Toole Á, Wawina-Bokalanga T, Mukadi-Bamuleka D, Amuri-Aziza A, Malyamungu-Bubala N, Mweshi-Kumbana F, Mutimbwa-Mambo L, Belesi-Siangoli F, Mujula Y, Parker E, Muswamba-Kayembe PC, Nundu SS, Lushima RS, Makangara-Cigolo JC, Mulopo-Mukanya N, Pukuta-Simbu E, Akil-Bandali P, Kavunga H, Abdramane O, Brosius I, Bangwen E, Vercauteren K, Sam-Agudu NA, Mills EJ, Tshiani-Mbaya O, Hoff NA, Rimoin AW, Hensley LE, Kindrachuk J, Baxter C, de Oliveira T, Ayouba A, Peeters M, Delaporte E, Ahuka-Mundeke S, Mohr EL, Sullivan NJ, Muyembe-Tamfum JJ, Nachega JB, Rambaut A, Liesenborghs L, Mbala-Kingebeni P. Sustained human outbreak of a new MPXV clade I lineage in eastern Democratic Republic of the Congo. *Nat Med*. 2024 Jun 13. doi: 10.1038/s41591-024-03130-3. Epub ahead of print. PMID: 38871006



# IFAPP TODAY

The Global Pharmaceutical Medicine Journal



- 10) <https://www.afro.who.int/health-topics/mpox-monkeypox>
- 11) <https://www.afro.who.int/health-topics/disease-outbreaks/outbreaks-and-other-emergencies-updates>
- 12) <https://www.who.int/emergencies/situations/Ebola-2019-drc>
- 13) W Preiser, C Baxter, J Nachega: Mpox outbreak in Africa was neglected – it could now turn into the next global pandemic. The Conversation, published 15 August 2024. <https://theconversation.com/mpox-outbreak-in-africa-was-neglected-it-could-now-turn-into-the-next-global-pandemic-236893>
- 14) Nachega JB, Sam-Agudu NA, Ogoina D, Mbala-Kingebeni P, Ntoumi F, Nakouné E, Njouom R, Lewis RF, Gandhi M, Rosenthal PJ, Rawat A, Wilson LA, Kindrachuk J, Liesenborghs L, Mills EJ, Preiser W, Rimoin AW, Sullivan NJ, Peeters M, Delaporte E, Baxter C, Harrison L, Hermans MP, Mohr EL, Gonsalves G, Ndembi N, Zumla A, Muyembe-Tamfum JJ; Mpox Research Consortium. The surge of mpox in Africa: a call for action. Lancet Glob Health. 2024 Jul;12(7):e1086-e1088. doi: 10.1016/S2214-109X(24)00187-6. Epub 2024 May 9. PMID: 38735300
- 15) <https://www.who.int/news/item/13-09-2024-who-prequalifies-the-first-vaccine-against-mpox>
- 16) Volz A, Sutter G. Modified Vaccinia Virus Ankara: History, Value in Basic Research, and Current Perspectives for Vaccine Development. Adv Virus Res. 2017;97:187-243. doi: 10.1016/bs.aivir.2016.07.001. Epub 2016 Aug 1. PMID: 28057259; PMCID: PMC7112317
- 17) <https://www.nytimes.com/2024/08/23/health/mpox-vaccines-who-africa.html>
- 18) <https://www.dw.com/en/mpox-germany-to-give-africa-100000-doses-of-vaccine/a-70055504>
- 19) <https://extranet.who.int/prequal/news/invitation-manufacturers-vitro-diagnostics-monkeypox-virus-nucleic-acid-detection-submit>
- 20) <https://www.who.int/news/item/13-09-2024-who-and-partners-establish-an-access-and-allocation-mechanism-for-mpox-vaccines--treatments--tests>

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## Why I Chose a Career in Pharmaceutical Medicine: My Story

For as long as I can remember, I've been driven by a passion to make a meaningful difference in people's lives through the practice of medicine. My journey into the pharmaceutical field began from my early days in Gaborone, Botswana, and has led to my current role as a Senior Director Medical Review within Global Patient Safety, in Cork, Ireland.

Time spent during my medical training, particularly as a community service volunteer helped shape my passion and vision for patient safety. Those experiences taught me that there's more to healthcare than just treating patients - it's about improving systems, creating opportunities for better outcomes, and ensuring that people have access to safe and effective treatments. After obtaining my medical qualification and working in Emergency Medicine, I pursued a Master's degree in International Health and Tropical Medicine at the University of Oxford. This was a turning point in my career. The course and having worked in diverse medical environments across Europe and Africa opened my eyes to the global health landscape and how



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critical drug development, regulatory policies, and patient safety are in shaping the future of healthcare, particularly in resource-limited settings.

Choosing Pharmaceutical Medicine was, in many ways, inevitable for me. It bridges my love for medicine with my desire to influence healthcare beyond the day-to-day patient interaction. In my professional roles, whether as a Clinical Research Physician, Investigator or now as a Senior Director Medical Reviewer in Global Patient Safety, I have the opportunity to contribute to the development of essential medicines and ensure that patient safety is always at the forefront. From working on global clinical trials, especially in areas like HIV and Gut health, I've seen firsthand how the advancements in Pharmaceutical Medicine can change lives. It's not just about research - it's about delivering tangible results that can improve the quality of care for patients globally.

Joining organisations such as the Association of Pharmaceutical Physicians of Ireland (APPI) has allowed me to learn and engage in meaningful discussions of promoting Pharmaceutical Medicine as a profession and speciality in Ireland. As an International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) National Member representative for the APPI, my role is to be the Ireland delegate to join quarterly national member meetings to engage and contribute to IFAPP's planned initiatives and innovative approaches. Being a member of the IFAPP has been a great opportunity for me and has allowed me to network and collaborate with other NMAs including participating in the IFAPP External Affairs Working Group (EAWG). This ability to collaborate across disciplines is essential in the practice of Pharmaceutical Medicine, where integrated efforts lead to the most successful outcomes. It is through organisations such as the APPI and IFAPP that has allowed me to explore and understand the diversity within the pharmaceutical field and one can't help but get excited about what the future holds for the profession.

I would encourage young professionals aspiring to join the pharmaceutical field to harness their skills and professional experiences. Whether one has a clinical skillset or not, you have the power to transform lives and shape the future of the pharmaceutical field. Keep pushing boundaries and stay inspired!

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## Navigating Your First Year: Insights and Strategies for Newcomers in Clinical Trials

Starting a career in clinical trials can be an exciting and fulfilling time. Your first position is a doorway to future opportunities. However, many young professionals recall feeling particularly insecure and stressed in the early years.

We asked young professionals to share insights on how to navigate and survive the first year. These discussions offer valuable tips on building essential skills, overcoming common challenges, and handling the pressures of a new role. Their insights will help you build a strong foundation for success in the fast-paced world of clinical trials.

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### Christiane, 31:

I started as an In-House Clinical Research Associate. At the moment I hold a Senior Clinical Research Associate position.

#### **What was the most challenging part during the first one to two years?**

I think to cope with all the regulations and documents that are necessary or important.

#### **What supported and motivated you during this period? Why did you continue in clinical trials?**

I like the general field of clinical research, being part of different trials in different teams, its very diverse and it's great to see when a trial is successful, or patients benefit from a new drug.

The first month (or even months) is usually dedicated to onboarding and trainings. You should learn basics and develop a solid understanding of clinical research prior to even starting in a new position. Gain a deep understanding of the phases of clinical trials, good clinical practice (GCP), and ethical guidelines such as the Declaration of Helsinki. Familiarise yourself with applied regulations and local laws that govern clinical research.

Clinical research is constantly evolving. Due to your location or workload you may not be able to attend conferences or summits. But you can take additional courses, read journals and subscribe to newsletters to stay informed on the latest trends and innovations. Groups like The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) or The Society of Clinical Research Associates (SOCRA) offer networking, certifications, and resources.

Many companies have a comprehensive mentoring system for new employees. If not, find a more experienced colleague to help you understand the ins and outs of the job.

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### Ivan, 34:

Like many other people I started my career in clinical trials in a Clinical Trial Assistant position. I have to admit that it is a good starting position. Almost five years later I work as a Senior Project Management Analyst.

#### **What was the most challenging part during the first one to two years?**

First of all, the most difficult part of doing my job in the first year was understanding the



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distribution of tasks between the different teams and what exactly I had to do.

And then secondly, understanding how actually to do that task.

### **What supported and motivated you during this period? Why did you continue in clinical trials?**

My colleagues onboarded, supported and helped me through this challenging time. I could always approach them for clarification on the tasks, how to use software, etc.

I also kept reminding myself that this is the first stage of my career, and it will get easier and easier over time. Everyone understands that this is a transitional position, you need to learn, gain skills and experience. And after that it will be possible to climb the career ladder or move to another department.

Communication is crucial at any position. You will collaborate with colleagues and line manager, Clinical Research Associates (CRAs), investigators, coordinators, sponsors, or regulatory authorities. Develop strong communication skills to ensure smooth operations.

Being adaptable and developing a problem-solving mindset is important. Clinical trials can encounter unexpected issues, such as patient dropouts or data discrepancies. Being flexible and able to troubleshoot is valuable.

Clinical trials require precise data collection and reporting. Attention to detail is critical in ensuring the validity and integrity of the study.

### **Anna, 32:**

I have over 8 years of experience in clinical trials. I started as a Clinical Data Coordinator. And now I hold the position of Principal Clinical Data Manager.

### **What was the most challenging part during the first one to two years?**

Probably, the most difficult thing I faced in the early years was that a small CRO, where I started my career, had limited resources in terms of training. There were many things I had to learn on my own.

### **What supported and motivated you during this period? Why did you continue in clinical trials?**

Among other things, I was attracted by the benefits and salary, which are definitely higher in industry than in academia.

Ultimately, you may not be happy in your current position. But there are many different roles in clinical trials, including study coordinator, CRA, data manager, regulatory specialist and many others. Exploring diverse roles within the clinical trials field can help you identify the career path that best aligns with your interests, skills, and long-term goals.

Remember, every expert was once a beginner, and it's okay to take things one step at a time!

**Author: Kateryna Uspenska**, PhD, Senior Clinical Project Manager at Gouya Insights, Vienna, Austria; member of the IFAPP Young Professional WG



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The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and the Dutch Association for Pharmaceutical Medicine (NVFG) are excited to announce that the International Conference on Pharmaceutical Medicine (ICPM) 2025 will be held from April 9 to 11, 2025, in the beautiful city of Amsterdam. The theme of ICPM 2025 is "Purpose for Future - in Pharmaceutical Medicine".

This theme underscores our commitment to advancing the field and shaping a future where innovative and effective medicines are developed and delivered with purpose and precision. ICPM 2025 promises to be an exceptional platform for exchanging knowledge, fostering collaboration, and exploring the future of Pharmaceutical Medicine. The conference will feature a meticulously designed scientific programme covering a broad spectrum of critical topics, including:

#### **Non-clinical Research:**

Explore the fundamental scientific discoveries that drive pharmaceutical innovation, with a focus on drug discovery, molecular biology, biochemistry, gene and cell therapies, and the optimisation of translational animal models. Discover how artificial intelligence can enhance preclinical development for the future.

#### **Clinical Research:**

Explore the design, conduct and analysis of clinical trials. Gain insights into patient recruitment, ethical considerations and data management, as well as the impact of pharmacogenetics and reimbursement discussions on clinical trial design. As AI, new technologies and decentralisation become the norm, what will the future bring?



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## Clinical Operations:

Address operational challenges and solutions in clinical trials, including project management, site selection and logistics. Learn about innovative strategies to improve trial efficiency and quality, including the impact of the updated ICH-GCP R3 guidelines.

## Health Economics:

Understand the economics of healthcare, focusing on cost-effectiveness, health outcomes and the economic impact of new therapies. Discuss global challenges in ensuring patient access to new medicines, health technology assessments, pricing strategies and the impact of real-world evidence on health economic evaluations.

## Medical Affairs:

Explore the role of medical affairs professionals in bridging the gap between clinical development and patient care. Discuss scientific communication, medical education, stakeholder engagement and future best practices in medical strategies.

## Pharmacovigilance:

Learn about the latest advances in drug safety monitoring, risk management and regulatory compliance. Gain insights into the detection and evaluation of adverse drug reactions and the implementation of robust pharmacovigilance systems.

## Regulatory Affairs:

Navigate the complex regulatory landscape with a focus on obtaining and maintaining product approvals. Discuss the latest trends and changes in regulatory guidelines, submission processes and compliance, particularly relevant given the conference's location in Amsterdam, home of the European Medicines Agency.

We invite researchers, practitioners and professionals in Pharmaceutical Medicine to respond to the Call for Abstracts. This is a unique opportunity to share your latest research, findings and innovations with a global audience. Details of how to submit an abstract can be found on our official conference website, and we invite you to submit abstracts before 1 December 2024. The key abstracts' themes will include RWE/RWD, secondary data use, EHD, Big Data, Digital therapeutics, practical implementation of AI, Medical Device research.

Join us in Amsterdam for ICPM 2025 to engage with renowned scientists, industry leaders and regulatory experts and be part of the discussions that will shape the future of Pharmaceutical Medicine.

For more information, to register and submit your abstract, please visit our official conference website at [icpm2025.com](https://icpm2025.com).

We look forward to welcoming you at ICPM 2025!



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## THE FLAG

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### **IFAPP Communication Working Group**

Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Francesco Butti, Brigitte Franke-Bray, Anna Jarczynska, Rita Lobatto, Hasan Mahmood, Kotone Matsuyama, Helio Osimo, Joanne Ramsey, Alexandra Reis Stoffel and Johanna Schenk (IFAPP TODAY Editor-in-chief).

IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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