IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

First Malaria Medicine for Newborn Babies and Young infants <5 kg Receives Approval

- Coartem® (artemether-lumefantrine) Baby becomes first malaria treatment approved for newborn babies and young infants
- Rapid approvals in eight African countries now expected under special global health scheme run by Swiss agency for therapeutic products (Swissmedic)
- Novartis plans to introduce infant-friendly Coartem Baby on largely not-for-profit basis to increase access in areas where malaria is endemic

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Geneva, 08 July 2025 – Coartem® (artemether-lumefantrine) Baby has been approved by Swissmedic as the first malaria medicine for newborns and young infants. The new treatment, also known as Riamet® Baby in some countries, was developed through an MMV (Medicines for Malaria Venture) and Novartis collaboration to treat the potentially deadly mosquito-borne disease.

Eight African countries also participated in the assessment and are now expected to issue rapid approvals under the Swiss agency's Marketing Authorization for Global Health Products procedure.[1] Novartis plans to introduce the infant-friendly treatment on a largely not-for-profit basis to increase access in areas where malaria is endemic.

"Malaria is one of the world's deadliest diseases, particularly among children. But with the right resources and focus, it can be eliminated," said Martin Fitchet, CEO of MMV. "The approval of Coartem Baby provides a necessary medicine with an optimized dose to treat an otherwise neglected group of patients and offers a valuable addition to the antimalarial toolbox."

Until now, there has been no approved malaria treatment for infants weighing less than 4.5 kilograms, leaving a treatment gap. They have instead been treated with formulations intended for use in older children, which may increase the risk of overdose and toxicity. Malaria vaccines are also not approved for the youngest babies.[2]

Some 30 million babies are born in areas of malaria risk in Africa every year,[3] with one large survey across West Africa reporting infections ranging between 3.4% and 18.4% in infants younger than 6 months old.[4] However, current data on malaria in young babies is extremely limited, as they are rarely included in clinical trials of antimalarial agents.[5,6]

"The available malaria treatments have only been properly tested in children aged at least 6 months because smaller infants are usually excluded from treatment trials," said Professor Umberto D'Alessandro, Director of the MRC Unit, The Gambia at the London School of Hygiene and Tropical Medicine. "That matters because neonates and young infants have immature liver function and metabolize some medicines differently, so the dose for older children may not be appropriate for small babies."

The new dose strength designed for young infants was developed by Novartis with the scientific and financial support of MMV, and as part of the PAMAfrica consortium, which is co-funded by the European & Developing Countries Clinical Trials Partnership and the Swedish International Development Cooperation Agency. The treatment is dissolvable, including in breast milk, and has a sweet cherry flavor to make it easier to administer.

"For more than three decades, we have stayed the course in the fight against malaria, working relentlessly to deliver scientific breakthroughs where they are needed most," said Vas Narasimhan, CEO of Novartis. "Together with our partners, we are proud to have gone further to develop the first clinically proven malaria treatment for newborns and young babies, ensuring even the smallest and most vulnerable can finally receive the care they deserve."

About the CALINA study

The Swissmedic approval is based on the Phase II/III CALINA study, which investigated a new ratio and dose of Coartem (artemether-lumefantrine) to account for metabolic differences in babies under 5 kilograms. It is indicated for the treatment of infants and neonates weighing between 2 and less than 5 kilograms with acute, uncomplicated infections due to Plasmodium falciparum or mixed infections, including P. falciparum. Coartem is known by the brand name Riamet in Switzerland and some other countries.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

About malaria
Malaria is a life-threatening disease caused by a parasite and spread to humans by certain types of mosquitoes. According to the most recent WHO data, there were 263 million cases of malaria and 597,000 deaths in 2023, almost all of them in Africa. Children under 5 years old accounted for about three in four malaria deaths in the region.[7]

For press enquiries, contact:
Elizabeth Poll | Medicines for Malaria Venture
Senior Director, Communications
Mobile: +41 79 907 59 92
Email: polle@mmv.org

MMV_Coartem Baby Swissmedic Press Release_1.pdf

1. Eight African countries participated in Swissmedic's Marketing Authorization for Global Health Products (MAGHP) procedure for Coartem Baby – Burkina Faso, Cote d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Tanzania and Uganda – and are expected to approve the medicine following approval by Swissmedic. These eight countries accounted for 47% of estimated cases in 2023, according to the WHO's Global Health Observatory
2. WHO. Malaria vaccines (RTS,S and R21)
3. Reddy, Valentina et al. Global estimates of the number of pregnancies at risk of malaria from 2007 to 2020: a demographic study. The Lancet Global Health, Volume 11, Issue 1, e40 - e47
4. Ceesay SJ et al. Malaria Prevalence among Young Infants in Different Transmission Settings, Africa. Emerg Infect Dis. 2015 Jul;21(7):1114-21.
5. Alessandro U, et al. Malaria in infants aged less than six months - is it an area of unmet medical need? Malar J. 2012 Dec 2;11:400.
6. Dobbs, et al. Plasmodium malaria and antimalarial antibodies in the first year of life. Parasitology. 2016;143(2):129-138.
7. WHO. Malaria.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

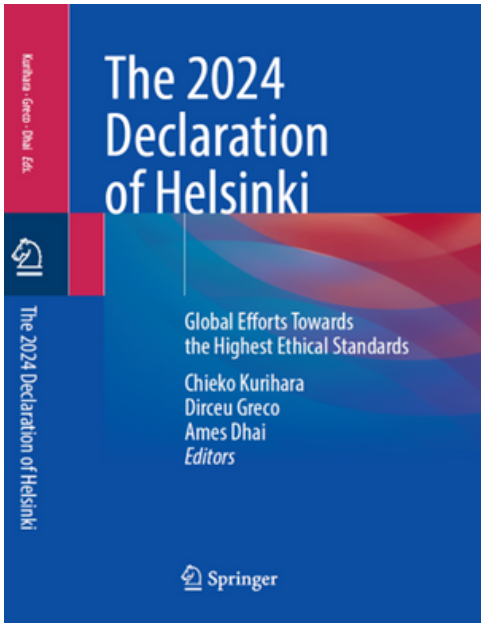
Global Research Ethics and Meaningful Engagement

Consensus Statement from three Sequential Meetings and a Springer Book Release

Three sequential meetings on "Global Research Ethics and Meaningful Engagement" were held on 25 August, 13 September and 15 September 2025. These meetings were initiated by IFAPP members (authors of this article), and were co-organised by the Brazilian Society of Bioethics, and the Japanese Institute for Public Engagement (Ji4pe). The results of these meetings will lead to a webinar on 29 September 2025, which will mark the launch of the book "The 2024 Declaration of Helsinki: Global Efforts Toward the Highest Ethical Standard" (Springer), for which the meeting collaborators are editors/contributors. We welcome your participation in the webinar!

The Statement of "Global Research Ethics and Meaningful Engagement" forms a part of the conclusion of the book and was expanded through the sequential meetings. You can find this Statement from the link below and can register your endorsement. We would be most grateful if you could endorse this Statement http://cont.o.oo7.jp/53_2/global_research_ethics.pdf!

The Statement will be addressed to international organisations such as the United Nations, UNESCO, CIOMS, WHO and the World Medical Association (WMA), which are involved in setting international research ethics standards. It is also envisaged that it will form the basis of IFAPP's renewed Ethics Framework, which will involve patients and the public to a higher degree, cutting-edge new technologies will be considered. To this end, cooperation between IFAPP and IFAPP's national member associations (NMAs) is highly desired.



This book, with two forewords from the WMA, contains an extensive analysis on the 2024 revision of the Declaration of Helsinki (DoH), from the perspectives of independent contributors: experts, bioethicists, patients and the public. The focus will be on new recommendations for community engagement, vulnerability, health databases and biobanks, as well as the protection of participants in comparative studies and the right to post-study access. The chapter authors will present their views on implementing the highest ethical standards in practice.
Please note: Contributors will introduce each chapter in a
Webinar to take place on:
Monday, **29 September 2025,**
UTC (Universal time coordinated): 11:30-14:30
Registration by 28 September 2025; free of charge:
https://forms.gle/LA2CJ52LGyMPLVnW6
The webinar is organised by the Brazilian Society of Bioethics, the Japanese Institute for Public Engagement (Ji4pe), and supported by IFAPP and its Japanese NMA JAPhMed, and other organisations.

◆ You can pre-order the book (forthcoming) from the link below.
https://link.springer.com/book/9789819692934

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Patient Public Declaration of Research Ethics as a Basis of the Statement

The Statement is based on the Patient Public Declaration of Research Ethics (1). This was issued by a group of patients and members of Ji4pe, who have attended an educational programme accredited by PharmaTrain (2), organised by the Ji4pe President Dr. Kyoko Imamura, who is a former IFAPP President (2018-2020). The group expressed prominent opinions from patient and public perspectives, far beyond the WMA's Declaration of Helsinki (3) and ICH-GCP(R3) (4).

They promote research oriented towards sustainable development goals (SDGs), taking into account ecological, social, and psychological impact including future generations. Their arguments are based on their experiences of patient communities' daily lives, as well as mixed hopes and concerns towards cutting-edge technologies, e.g., artificial intelligence (AI), genome editing, induced pluripotent stem cell (iPS), brain organoids, etc. The presentations and slides from the 25 August 2025 meeting, together with other parts of the programme, can be viewed via the link below. Other speakers from the Japanese group YORIAI Lab introduced international collaborations between industry and patient groups.

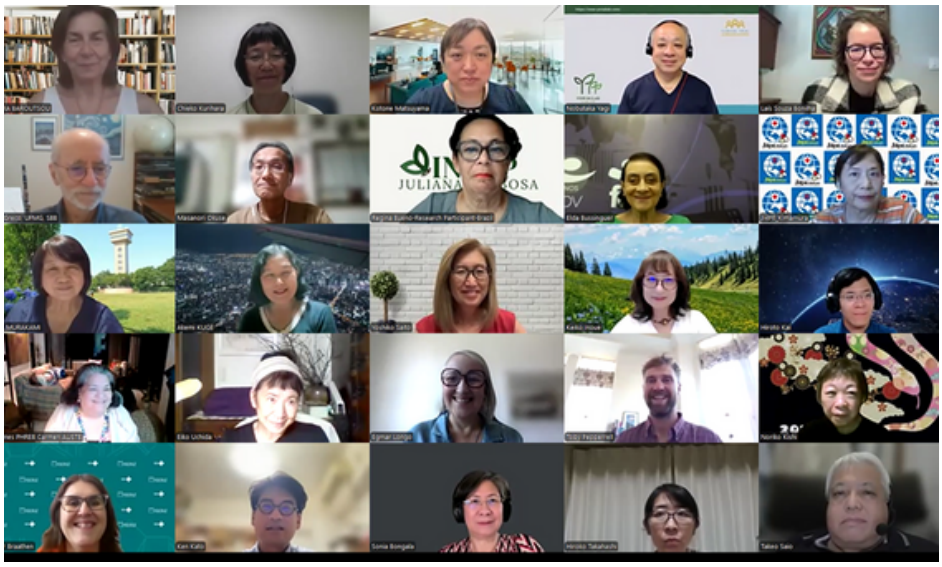
Here is the link to the original programme, where you can find each speaker and title of presentation, video-recording, and some of the presentation slides:
http://cont.o.oo7.jp/sympo/GREandME.pdf

Contributions from Brazilians initiatives, University Students, and IFAPP members

In the 25 August meeting, four prominent speakers introduced Brazilian state-oriented research ethics commissions, collaborating with a new initiative of research participants' association, and an excellent example of research participants' involvement. The Brazilian part of the meeting was coordinated by Prof. Dirceu Greco, editor of the aforementioned Springer book. Subsequently, a representative of the Universities Allied for Essential Medicines (UAEM) emphasised the need for more transparency of clinical trials and access to benefits from trial results. IFAPP's members (the authors of this paper) discussed patient involvement and equity in benefit sharing in the new trend of research including AI development. We look forward to IFAPP members participating in endeavours towards new frontiers in research ethics, and working together with all interested parties, especially patients and the public.

IFAPP TODAY

The Global Pharmaceutical Medicine Journal



Here are the speakers and participants who agreed to have their cameras on during the photo session at the 25 August meeting "Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development" (15 from Japan, 6 from Brazil, 2 from the Philippines, 1 from Greece, 1 from UK). Ten out of 25 are patient representatives. Eighty-four colleagues had registered, 49 participated in the webinar.

The meeting was supported by IFAPP, the Japanese NMA JAPhMed, and the Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM).

On 13 September 2025, the authors of this article, Prof. Dirceu Greco and Ji4pe patient representatives will hold a hybrid session, and the in-person conference on 15 September of the JAPERM International Symposium will be held in Yokohama, Japan. Both events are supported by the National Center for Child Health and Development. An updated statement will be disseminated for your endorsement after that. We would welcome your participation and endorsement!

References:

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

(2) PharmaTrain

(3) The World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. First adopted in 1964, last amended in 2024.

(4) ICH-GCP(R3): ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

Authors:

Chieko Kurihara, Specially-appointed Professor, Kanagawa Dental University, Editor-in-Chief, Clinical Evaluation, Japan

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

Varvara Baroutsou, Immediate Past President of IFAPP; CIOMS Executive Committee Member; Consultant in Internal Medicine and in Pharmaceutical Medicine, Athens Medicine School, NKUA Greece

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Webinar Announcement: Practical Challenges of Implementing ICH-GCP(R3) in Your Clinical Trials

Please note that this webinar, a special virtual Workshop following the webinar of 30th June 2025 on the ICH – GCP Revision, will start half-an-hour later than announced, i.e. **at 11:00 am CEST** (instead of 10:30 am CEST) on 18th September 2025. It will end at 15:30 CEST.

Performing ICH-GCP-compliant clinical trials remained to be a challenge, especially for academia and small and medium-sized enterprises but also for big pharma and investigators who often complained about an over-complicated quality framework, especially for late-phase and Phase-4 trials. The newly implemented R3 version requires from sponsor and investigator to decide how GCP requirements have to be applied in a way that is proportionate to the risks in this trial concerning participant protection, data reliability and scientific integrity. After the presentation of the new concepts and strategies of the R3 version in the webinar of 30the June 2025, this follow-up ICH-GCP(R3) workshop will provide the opportunity to learn about and discuss how these new strategies could be implemented in your clinical trial. For all agenda items there will be an introduction followed by discussions.

Faculty:
Ingrid Klingmann, MD, PhD, PharmaTrain, Belgium
Elisabeth Reus, Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland

11:00	Welcome and Introduction
11:05	Why is ICH-GCP(R3) requiring a mind shift in applying it to clinical trials?
•	Quality by design
•	Risk-proportionate approaches to all processes in trial preparation and conduct
•	Need for awareness and application of all ICH efficacy guidelines
11:50	What does “Quality by design” and “Critical to quality factors” mean in practice in your trial?
12:20	How to assess and decide on “risks” in your clinical trial and what does “risk proportionate” mean in practice?
13:00	Break
13:30	How to decide on required qualification and training needs?
13:45	How to enable reliable and seamless responsibility allocation and oversight between sponsor, service provider and investigator according to (R3), also in decentralised trials?
14:35	How to handle ethical aspects in relation to the Declaration of Helsinki and on eConsent?
15:00	How to apply the new Chapter 4 on governance for sponsors and investigators?
15:30	End of the Workshop

Register at the link below and ensure that you click on the date of 18th September 2025 which will open the registration for this workshop at 25.00 € in case you have not registered before for both webinars:

Register here

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

University Education vs Needs of the Pharmaceutical Supply Chain: Finding Common Ground

When discussing the adequacy and efficiency of university education, two aspects must be considered: teaching methods and educational content.

Let us start with the first aspect. First of all, the idea of progress must be measured against the context in which we are considering it. It is undeniable that, if you imagine a classroom from the 11th century, when universities were born, and compare it to a modern university lecture hall, you will not notice major changes. However, when comparing the remedies used in folk medicine centuries ago with today's advanced therapies capable of correcting genetic damage, the progress made in science is striking.

The criticism that teaching methods have not evolved has been circulating for years, but the pandemic intensified this widespread sentiment. Nowadays, students can access information independently through fast, powerful, and reliable tools. Therefore, to keep university education relevant, professors must go beyond simply transmitting knowledge and technical concepts. They must employ innovative, adaptable learning methods that cater to the students' needs, enabling them to solve increasingly complex problems, comprehend new discoveries, and actively contribute to societal progress. It is not that our predecessors did not provide this kind of education, but today it is essential to do so using innovative, engaging, and stimulating tools, which is not always easy. Innovative teaching does not just mean better use of digital tools; it means involving students more deeply, making them active participants through group or individual activities throughout the year, and encouraging them to share opinions and feedback, rather than relegating them to passive listeners who study the material months later in a mechanical way. Some progress is being made in this direction. Universities are evolving: Professors are offered training courses to improve their teaching quality, and software is being purchased to enhance classroom interactivity. However, I fear it is still not enough if we want to continue receiving praise from foreign professors for the preparation of our students when they study abroad.

Now let us move on to educational content. In this regard, all professors update their courses annually, and our curricula extend well beyond World War II. Continuing the analogy with history teaching, we even teach what is yet to come, not because we are clairvoyants, but because we study the literature and conduct research in our field. Students often graduate more up to date than many professionals in the sector. But that is not the point. Common criticisms from stakeholders include: "You teach concepts that aren't useful for the jobs they'll do!" or "Graduates don't know the basics needed to enter the workforce quickly!" Before continuing this line of thought, we must establish one thing: The university's role is to train professionals, not technicians. In our field, there are people who began their careers when stomach ulcers could only be treated surgically, before ranitidine was discovered, and who will retire with RNA (1) drugs, nanoparticles, or even CRISPR (2) and beyond. So, what should we teach students? Indeed, the principles underlying human physiology, the origin and development of diseases, and the fundamentals of the sciences involved in drug development are essential. This requires years of lectures and study. Just as a table with no legs or thin legs cannot bear much weight, a student without a solid foundation in basic scientific principles will not be able to support the "weight" of future knowledge. In the final years of

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Master's or other specialised degrees, more specific topics are addressed. Even then, it is essential to convey the logic behind the concepts. And I assure you, for subjects like mine, pharmaceutical legislation, it is neither easy nor immediate. And so, we reach graduation.

Will we have explained the new GCPs (3) and procedures for reporting adverse events in detail? Perhaps not. But we will have taught students that a drug cannot be administered without robust studies ensuring its quality, efficacy, and safety. What remains, the more technical and operational aspects, will come later through targeted postgraduate studies, practice, and experience.

In recent years, Italian universities have significantly expanded their postgraduate education offerings in collaboration with industry, aiming to provide students with practical and applicable knowledge essential for their careers. When offered in continuity with the degree, this education is more effective. There is no shortage of Master's programmes and advanced courses on topics of most significant interest to the health product supply chain. Postgraduate courses are more flexible and can be tailored year after year to meet real market needs. In the regulatory field in Milan (Italy), for example, we started in 1990 with a short advanced course focused solely on drug legislation. Piece by piece, we have built a one-year second-level Master's programme that now includes medical devices, cosmetics, supplements, and foods for special medical purposes, in addition to drugs. It also covers the cross-cutting topic of clinical trials, now conducted for all these product categories. Master's programmes must be designed in collaboration between universities and industry, with professors from diverse backgrounds and expertise. Sometimes there is a temptation to either extend the degree programme or, conversely, offer overly operational courses outside the university framework. We must not confuse Master's programmes with corporate training.

The educational challenges are significant, and we cannot afford to waste time. Everyone must be willing to step out of their comfort zone and rise to the occasion, aware that the knowledge and skills required in the pharmaceutical world are incredibly high, and that students, when properly stimulated, generally (though not always) respond with passion. A more interactive education can also help students identify their path earlier in a field like ours, which offers a wide range of career opportunities.

Abbreviations:
(1) RNA: Ribonucleic acid
(2) CRISPR: Clustered regularly Interspaced short palindromic repeats
(3) GCPs: Good Clinical Practices

Author: Paola Minghetti
Director, Department of Pharmaceutical Sciences, University of Milan, Italy
President, SCI Division of Pharmaceutical Technology
President, SITELF (Italian Society of Pharmaceutical Technology and Legislation)
Vice President, AFI (Association of Industry Pharmaceuticals)

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

World Patient Safety Day 2025: "Safe Care for Every Newborn and Every Child"

World Patient Safety Day 17 September 2025

World Patient Safety Day (WPSD) is celebrated every year on 17th September as one of the World Health Organization's global health days. Established in 2019, its foundation lies in the core medical principle "First, do no harm." The day aims to raise public awareness, encourage involvement, deepen global understanding, and inspire collective action to advance patient safety worldwide. Each year, a new theme draws attention to a critical area needing urgent action. This year WPSD holds a very strong message as it focuses on the safety of the most vulnerable population, i.e., every newborn and every child.

Before authorisation for human use, medicines must undergo thorough evaluation of quality, safety, and efficacy. Historically though, children were often excluded from such assessments, resulting in widespread off-label paediatric use. Shifts in the global regulatory landscape have led to some progress. For example, since the introduction of the EU Paediatric Regulation, sponsors are generally required to submit a Paediatric Investigation Plan. However, many treatments for children, particularly in rare diseases and in neonates and infants, still lack robust clinical evidence or formal approval, still relying on off-label usage. This gap has led to several issues, such as unclear dosing guidelines that increase the risk of harmful side effects - including fatalities - suboptimal treatment due to insufficient dosing, limited access to medical innovations, and the reliance on custom-made or pharmacy-prepared formulations that may not meet quality standards.

According to WHO, approximately 134 million adverse events occur annually due to unsafe care, particularly in low- and middle-income countries, resulting in unnecessary harm and even loss of life. A significant portion of these events involves paediatric patients, whose unique vulnerabilities demand tailored approaches to risk assessment and intervention. Several additional challenges hinder the reporting of adverse drug reactions (ADRs) in children:

- Young patients, especially infants and toddlers, often cannot articulate their symptoms or discomfort.
- A significant number of medications administered are either not officially approved for paediatric use or are prescribed outside their intended scope.
- Many herbal, traditional, and alternative remedies, such as phytotherapeutic, ayurvedic, anthroposophic, and homoeopathic products, are widely used due to the belief among caregivers and even some healthcare providers that they are gentler and less harmful.
- Medications are sometimes used inappropriately, such as the overuse of antibiotics.
- There is a lack of clinical research, and healthcare professionals may not have sufficient experience or training in documenting ADRs and adverse events (AEs).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

- A standardised list of essential medicines specifically for children has not yet been established in many countries.
- Suitable drug formulations and delivery tools tailored to paediatric needs are often unavailable.
- Often, there is no reference list of laboratory values that would trigger alerts for potential ADRs in children.
- Some inactive ingredients in medications, or in loosely defined traditional mixtures, may be incompatible or harmful for children.

To address these challenges, innovative strategies should be prioritised to accelerate safe and effective medicine development for children. These include establishing global paediatric safety-data networks to enable real-time signal detection of adverse events, adopting model-informed and age-adaptive trial designs that minimise risk while generating robust evidence, and developing child-friendly formulations tailored to different developmental stages. Leveraging digital health technologies, such as wearable devices and caregiver-reported outcome platforms, can further improve safety monitoring and empower families as active partners in paediatric research.

World Patient Safety Day 2025 is dedicated to raising global awareness about the critical importance of patient safety from the start - every child has the right to safe, quality health care from the very beginning. For this reason, this year's objectives are the following:

1. Increase global awareness of safety challenges in paediatric and neonatal care across all healthcare settings, with a focus on addressing the unique needs of children, families, and caregivers.
2. Encourage governments, healthcare institutions, professional organisations, and civil society to adopt sustainable approaches to enhance safety for newborns and children, integrating these efforts into broader patient safety and care quality initiatives.
3. Enable parents, caregivers, and children to play an active role in patient safety by promoting education, raising awareness, and fostering meaningful participation in care processes.
4. Advocate for expanded research efforts aimed at improving patient safety in paediatric and neonatal healthcare.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

World Patient Safety Day 2025 is a call to action for everyone, i.e. healthcare professionals, policy makers, parents, caregivers, health practitioners, healthcare leaders, educators and communities, to prioritise safe care for children. Paediatric safety must be viewed not only as an ethical obligation but also as a foundational effort to build future generations free from preventable harm. Together, we can transform the landscape of paediatric medication safety.

Authors on behalf of the IFAPP Pharmacovigilance Group:

Eirini Chatzopoulou

Brandon Michael Henry

Sources

1. Promoting safety of medicines for children (WHO)
2. World Patient Safety Day, 17 September 2025: "Safe care for every newborn and every child"
3. Regulation - 1901/2006 - EN - EUR-Lex

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Clinical Trials in Pregnant and Breastfeeding Individuals: ICH-E21 at Step 3

We have a precious opportunity of discussion on clinical trials in pregnant and breastfeeding individuals, for which the draft of ICH-E (efficacy) 21 Guideline is at the Step 3 status, just before closing public consultation. The ICH-E21 Guideline will provide clear instructions on how we can include pregnant and breastfeeding individuals in clinical trials with what kinds of reasoning of expected clinical benefits, pre-clinical and clinical information, as well as methodology of study designs, including safety and efficacy evaluation, recruitment, and other important aspects. The Guideline has been developed responding to international voices for promoting inclusion of pregnant and breastfeeding individuals in clinical trials, especially during the COVID-19 pandemic, as lack of evidence for these populations has hindered their access to optimal healthcare.

Our meeting was held on 30 August 2025 while Professor Daniel Fu-Chang Tsai, National Taiwan University College of Medicine, was staying in Tokyo, being invited by Sophia University for the study meeting on ethics of end-of-life care. Although the ICH-E21 Guideline refers other international documents regarding ethical considerations, it is critically important to reflect ethical, social backgrounds as well as standard medical practice and public health, and the environment of each region for better implementation of the Guideline, after its adoption. It should be noted that the CIOMS Guidelines 2016 version (1) were the first international guidelines to establish the policy of inclusion of vulnerable individuals in research as fundamental, requiring justification for their exclusion. The World Medical Association's Declaration of Helsinki (2) revised their policy in 2024 in accordance with CIOMS.

From left to right: Prof. Kurihara, Prof. Matsuyama, Prof. Tsai's wife and Prof. Tsai, Dr Motoki, and Dr Takeo Saio, psychiatrist/internist. Dr Motoki is engaged in the Working Group for ICH-E21 Guideline as a Topic Leader from PMDA/MHLW.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

At the time of publication of this issue of IFAPP TODAY, the following agencies still accept comments: ANVISA, Brazil, by 6 October 2025, FDA, United States, by 19 September 2025, Health Canada, Canada, by 25 September 2025, MHLW/PMDA, Japan, by 30 September 2025, TITCK, Türkiye, by 30 September 2025.

Information of ICH-E21 Guideline can be found at the ICH website:
https://www.ich.org/page/efficacy-guidelines

References:

(1) Council for International Organizations of Medical Sciences. International ethical guidelines for health-related research involving humans. 2016.
(2) The World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. First adopted in 1964, last amended in 2024.

Authors:
Chieko Kurihara, Specially appointed Professor, Kanagawa Dental University, Editor-in-Chief, Clinical Evaluation, Japan
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, Japan
Yoko Motoki, Deputy Director, Application Review Division I, Office of Relief Funds, Pharmaceuticals and Medical Devices Agency, Japan

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

A day in the Life of an MSL

The MSL position, when it is my turn to define it, beyond explaining what the acronym means, which would be a translation as a medical-scientific liaison, I define it a bit as a scientific advisor since I have to be up to date and updated on the latest news that are published and that are known in the respiratory field, On the one hand, to act as a loudspeaker for these new developments and discuss them with health professionals, but also with other functions within my company.

I arrived at my current job thanks to my previous studies. I studied Molecular Biology and Biochemistry and then I did a master's degree and a doctorate in Immunology. And when I was finishing my doctorate, I began to be interested in the MSL position, since it allowed me to combine the two things I liked to do, which was, on the one hand, research, from a clinical point of view in this case, with dissemination and teaching, because, in the end, we have this role of communicators, educators or transmitters of knowledge.

My day-to-day life as an MSL could start by taking a train to travel to some part of Spain, other than the one where I currently reside, to visit an opinion leader and find out, precisely, his/her opinion on the latest publication in the field of asthma or in the field of chronic obstructive pulmonary disease (COPD), and discuss with him/her the results of a clinical study or of any study that has been published on this topic. Afterwards, I could have a clinical session in the Pneumology Department to explain, for example, the latest developments that have been published in this year's asthma management guidelines.

And the day might end by paying a visit to a researcher or a doctor who is participating in a study that we, as a company, are sponsors for, see how recruitment is going, whether they are having problems, if it is a feasible study, or if they have any concerns or suggestions for improvement. And finally, I could end the day by going back to the hotel and making a video call with the sales network team to give them training in these latest asthma management guidelines that have been published.

Author: Cantero Pérez Jon, MSL at CHIESI España S.A.U., Spain

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

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

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

BADI Congress Announcement

Upcoming Congress on Pharmaceutical Legislation and Future Challenges
15th Anniversary of Annual Meeting of BADI (Bulgarian Association of Drug Information)
Sofia, Bulgaria, 9 October 2025

BADI is a non-governmental, non-profit organisation that unites over 60 corporate and 90 individual members. Its primary goal and mission are to work towards enhancing the qualification and professional competence of its members, as well as engaging in activities related to medicines regulations in public health.

BADI supports scientific research, education, and regulatory activities in the fields of pharmaceuticals, medical devices, food supplements, cosmetics, and other products related to public health. We have created a unique platform for a constructive dialogue between regulatory authorities, universities, industry professionals, and similar professional and non-governmental organisations.

Since its establishment in 2010, BADI has held over 120 training events (seminars, modular training courses, conferences, roundtables, discussions, and meetings), with more than 7,400 participants. These events have featured over 550 lecturers, including representatives from industry, academia, and regulatory authorities both in Bulgaria and abroad. Among our long-standing lecturers are over 120 internationally recognised professional drug regulatory experts from the UK, Germany, Denmark, Portugal, Switzerland, Poland, Finland, Norway, France, Austria, Hungary, Sweden, the USA, and more.

BADI is now pleased to announce its 15th anniversary at the upcoming congress that will take place in Sofia, Bulgaria, on 9 October 2025. The event will bring together key experts, policymakers, and industry leaders to discuss the latest developments in pharmaceutical legislation and the challenges ahead for the sector.

This year's congress will feature high-level speakers from European regulatory bodies and institutions, including the Executive Director of the European Medicines Agency (EMA) Emer Cooke and Mag Pharm. Bogdan Kirilov from the Bulgarian Drug Agency (BDA), who are expected to attend in person. Members of the Committee for Medicinal Products for Human Use (CHMP) are also part of the programme sharing their experiences.

Discussions will focus on critical issues such as:
✅ New Provisions in the General Pharmaceutical Legislation – How will they shape the industry in the coming years?
✅ Regulatory Challenges and Market Access – Insights from leading CHMP members.
✅ Innovations and Future Policy Directions – Perspectives from the EU and international health authorities and EFPIA.

The congress will be in English language.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

For more details, the draft programme and registration for the event, please visit

https://www.badibg.org/2025/ENG_15th_ANNIVERSARY_OF_BADI_DRAFT%20PROGRAM_01.09.2025.docx

The event will take place in the Grand Hotel Millennium in Sofia, Bulgaria, providing a central and well-equipped venue for discussions and networking.

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

Register here

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

THE FLAG

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

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

Follow us on: