IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

IFAPP International Ethics Framework: a Professional Ethical Guide for Medicines Developers

When training medicines developers the lecturers focus on educating the basic ethical principles of clinical research laid down in the Declaration of Helsinki (1) and in the Belmont Report (2). In addition, they discuss trial methodology based on the ICH-GCP (3) guidelines. However, do these documents cover the variety of ethical questions the medicines developers might face in their professional lives? The aim of our recently published paper is to discuss the professional significance and application of a collection of ethical advice published by the IFAPP Ethics Working Group (Kerpel-Fronius and Becker, 2025; Becker et al. 2003; Kerpel-Fronius et al. 2018).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Each drug development project encounters different ethical problems since this complex profession is embedded in an intricate scientific, sociological and ethical environment. The most important friction surface, occasionally creating severe ethical collision, lies in the double link of human medicines development to profit-oriented pharmaceutical industry and healthcare-based medical care. Both the Declaration of Helsinki and the Belmont Report provide ethical recommendations, which guide the members in their common goal of developing effective and safe medicines. However, to find the ethically correct path for fulfilling the specific goals of both major social players is sometimes very difficult. Where is the acceptable limit between pursuing the financial goals of the industry and the acceptable risk of possibly useless suffering of trial participants when the results are equivocal?

Moreover, we must face frequently additional scientific-ethical problems. Both industrial and healthcare representatives follow a scientific hypothesis in drug trials. The team performing a study must continuously evaluate whether the scientific vision underlying a clinical trial remains valid during the progression of a trial. To make timely correct ethical decisions in an environment heavy with different expectations is a significant moral burden for the medicines developers working either in the industry or in healthcare.

Many additional ethical challenges arise during the integration and propagation of registered new medicinal products in the broad clinical practice. The existing ethical guidelines cover advertising problems adequately. However, an additional real danger comes from staunch science-optimists, who occasionally grossly overstate the real value of a new drug or drug groups prophesising breakthrough in the treatment of a disease. Unfortunately, these scientific visionaries often underestimate the possible risks of the new medicines. This attitude might lead to extensive overuse of medicines causing a financial burden to the society with small or no improvements of health.

More dangerously, the unsupported positive claim might syphon away the available health care budget for more effective use. In addition, when the scientific bubble bursts it will leave a deep mistrust in medicines development and will open the gate for the propagation of fake news. Several recommendations of the IFAPP Ethics Framework relate to this problem emphasising trustworthiness and the priority of scientifically correct evaluation of data even if it might contradict industrial and/or scientific interests.

In the development and application of several modern drugs, for example in gene therapies, intensely coordinated cooperation of several scientific disciplines is necessary. The IFAPP Ethics Framework recommends that the cooperation should be organised in a way, which permits the differently trained experts to pursue a joint goal, share ethical responsibilities without violating the principles and ethical guidance of their different professions. It also emphasises that medical and scientific participants should respectfully integrate representatives of patient organisations into the team considering their specific interests and sensitivities.

These few examples demonstrate the principle of the IFAPP Ethics Framework. It does not provide ready solutions but offers suggestions and directions for continuing moral evaluation of the problems. It emphasises that in most cases, there are no clear ethical answers how to solve the myriads of complex ethical issues that might emerge in medicines development. Much more, there are possible approaches, which have to be carefully weighted. Therefore, the IFAPP Ethics Framework essentially presents a collection of advice grouped in five different sections dealing with: duty of medical care; scientific competence and diligence; impartiality in formulating opinions; probity exhibiting high moral standards and trustworthy behaviour; finally, personal integrity and accountability in the workplace.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The suggestions aim to encourage and support the reader to continue the further analysis of the situation to find the right ethical answer.

The question is how to encourage the use of this professional ethical code? It is not well suited for memorising concrete ethical recommendations for situations which pharmaceutical professionals might encounter in various projects. It seems more helpful to initiate group discussions and evaluating the suitability of the suggestions of the Ethics Framework for analysing and solving various moral problems. Becker and Barrett started already in 2012 a very successful polemic on the difficulties of trial site selection addressing the readers of the IFAPP's ETHICS CORNER (Becker and Barrett 2012 and 2013). We suggest integrating the IFAPP Ethics Framework on proper ethical behaviour into the education of future medicines developers.

ABBREVIATIONS

1) Declaration of Helsinki
2) Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
3) ICH-GCP: ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

REFERENCES

Kerpel-Fronius S and Becker AL. The Value and Importance of a Professional Ethical Code for Medicines Development: IFAPP International Ethics Framework.
Becker AL, Barrett J, De Botha J, Brun J, Cairds D, Chan A, et al. International Code of Ethical Conduct for Pharmaceutical Physicians, 2003. Available from: https://ifapp.org/wp-content/uploads/2016/12/IFAPP- Final- Ethics-Code-April-2003-2.pdf.
Kerpel-Fronius S, Becker AL, Barrett J, Brun J, Carlesi R, Chan A, et al. The shared ethical responsibility of medically and non-medically qualified experts in human drug development teams. Front Pharmacol. 2018. https:// doi. org/ 10. 3389/ fphar. 2018. 00843 (Supplementary Material of this article contains the full text of the IFAPP Ethical Framework at: https://www.frontiersin.org/articles/10.3389/fphar.2018.00843/ full # supplementary-material).
Becker AL and Barrett J. IFAPP's ETHICS CORNER, Ethical Quandary: Site Selection Dilemmas. IFAPP WORLD, pp3-4. June, 2012; http://ifapp.org/Publications/IFAPP-World).
Becker AL and Barrett J. IFAPP's ETHICS CORNER, Ethical Quandary: Site Selection Dilemmas. IFAPP WORLD, pp6-8. April, 2013; http://ifapp.org/Publications/IFAPP-World).

Authors:
Sandor Kerpel-Fronius1+, MD, PhD, DSc, FFPM, and **Alexander L Becker**2+ MB. BCh, FFPM, GFMD, Dip Business Management.
1. Department of Pharmacology and Pharmacotherapy. Semmelweis University Budapest, Hungary
2. Consultants in Pharmaceutical Medicine, Dover Heights, Australia
+ Both authors are members of the IFAPP Ethics Working Group

Dr. Sandor Kerpel-Fronius

Dr. Alexander L Becker

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Educated Patients, Better Healthcare - EUPATI Cyprus

EUPATI (1) Cyprus is dedicated to empowering patients and advancing healthcare through education and advocacy. As a leading force in patient engagement, the organisation equips individuals with the knowledge and skills needed to contribute meaningfully to research, policy, and healthcare development. Through impactful programmes and strategic collaborations, EUPATI Cyprus is shaping a future where patients are recognised as essential partners in healthcare innovation and decision-making.

The EUPATI Cyprus Board consists of dedicated professionals from academia, industry, and patient advocacy with diverse expertise in healthcare, education, and patient rights. Their collective experience shapes policies and strategies aimed at strengthening patient education and engagement across Cyprus. Since its establishment, EUPATI Cyprus has played a pivotal role in shaping the healthcare landscape by fostering meaningful collaborations with key stakeholders. Operating from the offices of the Cyprus Federation for Patients' Associations (CyFPA), the organisation benefits from a close partnership with CyFPA, which is also a member of its Board. This strategic alliance strengthens EUPATI Cyprus's ability to amplify the voices of patients nationwide.

Ms Souzi Makri, President of EUPATI Cyprus at a recent press conference

Patient Expert Educational Programme

EUPATI Cyprus's Patient Expert Educational Programme is a transformative initiative designed to equip patients and advocates with the knowledge necessary to actively participate in healthcare discussions and advocacy. Developed in alignment with EUPATI Central standards, the programme was shaped through a comprehensive 2023 survey and a series of workshops involving academics, patient representatives, and industry professionals.

A dedicated scientific committee, formed to ensure the programme's alignment with best practices, has played a crucial role in guiding its development and maintaining its high educational standards.

The programme consists of seven key modules: Introduction to EUPATI, Personal Development, Health Technology Assessment (HTA), Research and Patient Advocacy, Development and Licensing of Pharmaceuticals, Digital Literacy, and National Strategies. These modules are carefully designed to offer participants a well-rounded education on the core aspects of healthcare systems, patient advocacy, and the increasingly important role of digital tools in health. By combining practical knowledge with theoretical understanding, the programme empowers participants to engage meaningfully in shaping healthcare policies and decisions.

Offered twice a year, the programme provides certified education for patient organisations and their representatives, helping to create a network of well-informed patient advocates. After two successful editions, EUPATI Cyprus is set to launch its third programme in March 2025, with the aim of further expanding the community of educated patient advocates in Cyprus.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

EUPATI Toolbox

Another significant milestone in its mission was the successful translation of the renowned EUPATI Toolbox into Greek, making vital patient education resources accessible to Greek-speaking communities in Cyprus and beyond. Covering essential topics such as clinical trials, regulatory systems, and HTA, the Toolbox empowers patients with the knowledge needed to engage in healthcare decision-making.

This initiative underscores EUPATI Cyprus's commitment to inclusivity and accessibility, benefiting patient organisations, healthcare professionals, researchers, and policy makers by fostering stronger collaboration and more informed discussions.

EUPATI Cyprus continues to drive patient empowerment through impactful events and strategic partnerships. In November 2024, the organisation, in collaboration with CyFPA, hosted a landmark Conference on Patients' Rights, bringing together academics, doctors, EUPATI Fellows, and patient representatives.
This event reinforced the importance of educated and informed patients in shaping healthcare policies. Further strengthening its role in patient education, EUPATI Cyprus partnered with EUPATI Central to organise an insightful webinar on HTA, facilitating discussions on patient involvement in evaluating new medical technologies.

Collaboration is at the heart of EUPATI Cyprus's success. The organisation partners with a diverse network of stakeholders, including the Ministry of Health, universities, and pharmaceutical companies, to integrate patient perspectives into healthcare development.

The support of major sponsors such as the Cyprus Association of Research and Development Pharmaceutical Companies (KEFEA) has been instrumental in delivering high-quality educational programmes and initiatives.
Contributions from CyFPA, Hoffmann-La Roche, Alector Pharmaceuticals & Papaloisou (Astrazeneca in Cyprus), the European University of Cyprus, and the University of Nicosia further highlight the growing recognition of patient-centric approaches in healthcare.

Patient Expert II

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Looking ahead, EUPATI Cyprus remains committed to advancing patient education, increasing patient involvement in research, and advocating for meaningful healthcare policies. By fostering collaboration and providing accessible educational opportunities, the organisation is working towards a future where patients are valued as equal partners in shaping healthcare systems. As our motto proudly states: "Educated Patients, Better Healthcare.

Abbreviations:
1) EUPATI: European Patients Academy on Therapeutic Innovation (www.eupati.eu)

Author:
Andri Protopapa, Administration Officer, EUPATI Cyprus

EUPATI CYPRUS
European Patients' Academy on Therapeutic Innovation

Educated patients. Better healthcare.

The Power of Mentoring: Guiding and Growing Together

Author: Dr Mariangela Amoroso

Mentoring is an innovative training support process where a person (the mentor) follows, advises and promotes the development of another person (the mentee) in a specific complex area, establishing a relationship that is not one of subordination but one of friendship, cordiality and support.

It is a relationship with a high degree of **mutual trust** and **respect** in which a more experienced or more competent person guides a less experienced or less competent person. It is a special and often **transformative relationship** that goes far beyond the simple transfer of knowledge and becomes a process of **mutual growth, emotional support** and **personal and professional development.**

The origins of mentoring can be traced back to ancient Greece. The term derives from the name Mentor, a character in Homer's Odyssey. When Odysseus left for the Trojan War, he entrusted his son Telemachus to the care of Mentor, a trusted friend. Mentor became Telemachus's counsellor and guide, helping him to grow and develop in his father's absence.

This guiding and supportive relationship inspired the modern concept of mentoring, which has been applied in a wide variety of contexts, including educational institutions, the workplace and personal development, and has become a fundamental practice for individual growth and success through structured mentoring programmes, guidelines and resources to support the mentoring relationship.

Many organisations use mentoring programmes to support the professional development of employees, improve employee satisfaction and retention, and ensure the continuity of the

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

organisation's skills. These programmes can be particularly useful for new hires, young talent and employees aspiring to leadership roles.

Universities and schools often use mentoring programmes to support students on their academic and careers paths. Mentors can be professors, alumni or industry professionals who provide advice and support to students. Professional associations may also offer mentoring programmes for their members to facilitate networking and professional development. These programmes help professionals grow in their careers and stay abreast of the latest industry trends.

Why is mentoring important and how can you make the most of these valuable interactions?
One of the most obvious benefits is access to the expert guidance and wisdom of those who have been down a particular path. Mentors can offer practical advice based on their personal experience, helping mentees to avoid common mistakes and make informed and deliberate decisions. This guidance is particularly valuable in the early stages of a person's career, when every step can seem uncertain and every decision weighty.

Mentoring fosters a continuous learning environment. Mentees have the opportunity to acquire new skills, explore innovative ideas and discover different perspectives. This learning process is not one-way; mentors often find the interaction enriching as they learn from mentees. The ongoing exchange of knowledge and ideas enriches both parties and creates a powerful dynamic of continuous growth.

Having a mentor can greatly expand a mentee's network of contacts. Mentors, often well connected in their field, can introduce mentees to key people and open doors to new professional and personal opportunities. This established network can be crucial in accelerating a mentee's career and providing opportunities that might otherwise be difficult to access.

Facing challenges in your career or personal life can be daunting. A mentor provides essential emotional support, acting as a sounding board in moments of uncertainty. This support can make the difference between giving up on a goal and finding the strength to persevere. In addition, mentors often motivate their mentees to push beyond their limits and believe in their abilities.

Beyond the professional benefits, mentoring also promotes personal development. Mentors help mentees identify and develop their strengths, overcome their weaknesses and become better versions of themselves. This process of self-discovery and self-improvement is fundamental to a fulfilled life. A mentor can provide a crucial change of perspective, helping mentees to see situations in a new light. This can be particularly useful when mentees are faced with difficult decisions or complex and intricate problems. Having someone to offer a different perspective can help unlock new solutions and approaches that may not have been considered.

However, mentors and especially mentees must establish clear and meaningful goals for the journey to be valuable by identifying specific and achievable objectives to be realised.

Mentoring is not just about the present but also the future. Training young professionals through such a process is essential for preparing the next generation of leaders. Today's mentees can become tomorrow's mentors, creating a continuous and virtuous cycle of support and growth. This continuity is fundamental for the sustainable development of organisations and communities and encourages a sense of commitment and responsibility. Mentees, knowing they have a mentor

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

to rely on, tend to take their goals more seriously and work with greater dedication to achieve them. At the same time, mentors feel responsible for the success of their mentees, promoting a relationship of mutual responsibility and trust. Additionally, it can also play a key role in promoting inclusivity and diversity. Mentors from various social and professional spheres can help bridge representation gaps and foster a more genuinely inclusive environment.

Finally, mentoring has a lasting impact. The lessons learned and advice received during a mentorship programme stay with mentees for life. These teachings influence not only the mentees' careers but also their personal growth and the way they face challenges and opportunities.

In conclusion, mentoring is a powerful tool for growth and development that goes beyond the simple transmission of knowledge. It is a relationship of close reciprocity that enriches both mentors and mentees, offering professional, personal, and emotional benefits. Investing in mentoring means investing in the future, as it creates a continuous chain of support and growth that can transform careers, lives, and communities.

If you have ever thought about finding a mentor or becoming a mentor, remember that every great journey begins with a small step. Mentoring relationships can start informally, through a genuine connection and a sincere and shared desire for growth.

The Benefits of Mentoring

Mentor	Mentee
• Cognitive re-working of lived experience • Opportunity to acquire a personal space for reflection • Mutual learning • Personal satisfaction in helping others • Recognition and appreciation • Networking opportunities	• Safe space for development • Guidance, vicarious experience, and faster growth • Feedback and increased self-awareness • Improved self-confidence and personal satisfaction • Networking opportunities • Learning to manage difficult situations

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Key Elements of a Mentorship Programme

- **Clear Objectives:** A good mentorship programme has clear and defined objectives for both mentors and mentees. These objectives can include the development of specific skills, improvement of work performance, or support in personal growth.
- **Selection and Matching:** Participants are selected and matched based on their skills, experiences, and goals. This process may involve interviews, questionnaires, or other forms of assessment to ensure a good match between mentor and mentee.
- **Training and Support:** Mentors receive training and support to understand their roles and responsibilities through workshop sessions.
- **Structure and Planning:** The programme has a clear structure with regular meetings and short- and long-term goals. This helps keep the mentoring relationship focused and productive.
- **Evaluation and Feedback:** The programme includes mechanisms for evaluation and feedback to monitor progress and make any necessary improvements. This can include surveys, interviews, or periodic reports

Author:
Mariangela Amoroso MD, Medical Director, Sanofi, SIMeF Delegate

History Helps Us Prepare for the Future

Finland is a Nordic country with an area of 338,472 km² and a population of 5.6 million people. Approximately 75 % of the country is covered by forests, and there are over 168,000 lakes. Finland became a member of the European Union in 1995 and adopted the common currency (€) in 2002 among the first member states. These historic events brought the rest of Europe closer and made it more accessible to Finnish citizens, providing collaborative opportunities never seen before.

EUPATI (European Patients' Academy on Therapeutic Innovation) is a pan-European project launched in 2012 under the Innovative Medicines Initiative (IMI). Its goal is to increase the engagement of patients and citizens in the research and development of medicines and medical devices through education. As Europe and pan-European projects became easily accessible to Finnish associations, EUPATI activities were introduced in Finland in 2018 by an employee of the Association of Cancer Patients in Finland as part of an ongoing project back then. From the outset, it was emphasised that, despite being hosted by an association focused on cancer, EUPATI Finland would remain free from any specific diagnosis. One of the Finnish EUPATI National Platform's greatest strengths has been its active and committed Executive Board, as well as its operation under a well-established organisation. This means that, in Finland, EUPATI is not an independent legal entity, despite having its own board, annual plans, meetings, and budget. Our activities are funded by several pharmaceutical companies, and this collaboration enables one of our employees to dedicate part of her working time entirely to EUPATI activities. We appreciate having multiple partners listed on our website, as it enhances transparency and credibility. On the EUPATI Executive Board, the pharmaceutical industry is represented by its own association, Pharma Industry Finland. This equal and transparent practice has worked extremely well.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The Executive Board has played a central role in enabling national study groups that educate on EUPATI topics, ranging from preclinical to clinical trials, market access, national availability, and reimbursement. Board members contribute their own expertise and leverage their professional networks. One of EUPATI Finland's greatest achievements is its agility in addressing current topics by organising educational study groups, providing patients and citizens with clear, free information on relevant societal issues. For instance, during the COVID-19 pandemic, we organised a webinar on COVID-19 vaccines and the vaccination of cancer patients – an excellent example of collaboration between EUPATI Finland and the Association of Cancer Patients in Finland to provide tailored information for a specific need.

The COVID-19 pandemic accelerated digitalisation significantly. In a way, this brought partners from different parts of the world closer together and created new ways of collaborating and working. For EUPATI Finland, all activities moved online, and this has remained unchanged even after the pandemic. Board meetings and study groups are now conducted entirely online, which has made participation more accessible. Finland is 1,157 km long and the least densely populated country in the European Union, and EUPATI activities are primarily organised in the capital, Helsinki.

It appears that, interlinked to accelerated digitalisation, also the rhythm of changes has speeded up. We have less and less time to prepare and adapt to changes. Simultaneously, the value of patient and public engagement has become increasingly appreciated.

Being a member state of the European Union has brought numerous benefits as well as obligations. The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and applies from 12 January 2025, requiring changes to the national evaluation system. We now find ourselves at a crucial moment where we appreciate the foundation we have built over the past seven years. Thanks to Finnish EUPATI National Platform (ENP), we are far better equipped to educate people than we would have been without it.

Author:
Jenni Tamminen-Sirkiä, Executive Director, Association of Cancer Patients in Finland

References:

Ministry of Agriculture and Forestry of Finland (n.d.) About Finland. Available at: https://mmm.fi/en/eu2019fi/about-finland

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The Evolving Landscape of Clinical Trials in the Middle East and North Africa

The Middle East and North Africa (MENA) are among the latest emerging markets in clinical trials. With over 22 countries speaking one language, the region presents diverse profiles in terms of healthcare infrastructure, physician-to-patient ratio, and regulatory guidance and timelines. Notably, the regulatory framework in the MENA differs significantly across countries. While all have established National Regulatory Authorities, their capacity and resources vary greatly.

As such, the MENA may be classified into three sub-regions: Gulf Cooperation Council (GCC) countries [KSA (1), UAE (2), Kuwait, Bahrain, Qatar and Oman], the Levant region [Jordan, Lebanon, Syria and Palestine], and North Africa [Egypt, Libya, Tunisia, Algeria and Morocco]. In each of these regions, a few countries emerge in terms of clinical research activity, constituting focal points for the entire region.

Such emergence is driven by patient population and disease prevalence, investigators' experience, and healthcare infrastructure. As many governments in the region regularly work to enforce clinical research regulations and the pharmaceutical industry continues to seek untapped patient populations, clinical research activity is expected to expand and cover the entire MENA region.

As a vast geographical territory with a large population of over 500 million, the MENA region has great access to patients of different ages and different disease backgrounds.

Due to the high prevalence of relevant conditions and diseases such as oncological conditions and rare genetic disorders, often linked to consanguinity, there is increased interest in trial participation and the size of treatment-naïve populations. As a result, the MENA region experiences rapid patient enrolment and high patient retention rates, driven by cultural and economic factors.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

MENA also offers a diverse patient pool with varying demographics and disease profiles. This, coupled with the potential for cost-effective clinical trial conduct, makes the region an attractive destination for pharmaceutical research. However, it is crucial to acknowledge the diverse regulatory landscapes across the region. The WHO (3) plays a vital role in offering guidance and technical assistance to enhance regulatory capacity in the region, aiming to harmonise regulatory frameworks and facilitate the efficient conduct of clinical trials.

Given the limited footprint of large pharmaceutical companies and multinational CROs (4), there is a low number of competing trials, hence this region is still considered to be an untapped resource for clinical trials.

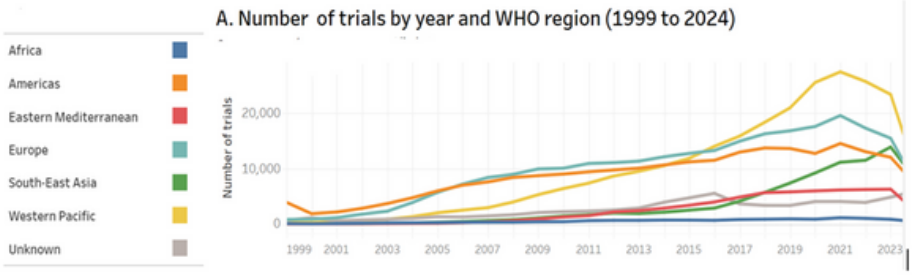
Not forgetting the state-of-the-art infrastructure in new modern hospitals and further new hospitals in the region being built, the environment for conducting clinical research is ever improving.

Most of the hospitals are now either already accredited by the Joint Commission International (JCI) or in the process of seeking JCI accreditation with almost all major hospitals having a dedicated clinical research department.

Investigators in the region are well qualified and mostly Western-trained with a high level of English and French proficiency.

However, despite the above-mentioned MENA characteristics, the region still hosts less than 1.00% of clinical trials globally.

Country	Population	GDP (5), 2023 data in million US$	Healthcare expenditure 2021 per capita	Industry-sponsored clinical trial global ranking	Industry-sponsored clinical trial share
Egypt	114,535,772	396,002.50	179.68	63	0.026%
Lebanon	5,773,493	20,992.42	307.13	60	0.037%
Jordan	11,439,213	50,967.48	299.07	68	0.017%
KSA	33,264,292	1,067,582.93	1,442.00	59	0.039%
UAE	10,483,751	514,130.43	2,351.81	73	0.011%
Kuwait	4,853,420	163,704.88	1,860.78	103	0.001%
Qatar	2,656,032	213,002,809.33	1,934.08	98	0.002%
Bahrain	1,577,059	46,079.87	1,146.47	127	0.0001%
Oman	5,049,269	108,810.92	852.62	81	0.005%
Tunisia	12,200,431	48,529.60	265.46	69	0.014%
Algeria	46,164,219	247,626.16	204.57	78	0.008%
Morocco	37,712,505	144,417.10	221.11	76	0.009%



IFAPP TODAY
The Global Pharmaceutical Medicine Journal

That said, most of the MENA countries such as KSA, Egypt, UAE, Tunisia, and Jordan have started looking at action plans to enhance the local environment to be favourable to clinical trial sponsors through streamlining the IRBs (6) and site start-up processes (contracting, ethics approvals), capacity building, clinical trial registries and increasing public awareness.

KSA's vision 2030 and national health priorities related to the research, development, and innovation (RDI) sector continue to be a focus, therefore, the Saudi National Institute of Health (SNIH), was established in August 2023, to encourage translational research and clinical trials in the field of health with the goal of creating therapies tailored to the unique health and economic circumstances of the Saudi community.

The SNIH aims to address the existing shortage of clinical trials, which will position KSA as a hub for medical innovation and biotechnology in the region.

Egypt's first Clinical Trial law was ratified in December 2020 followed by the Clinical Research Legislation in March 2022 mandating a more structured regulatory ecosystem with two main bodies:

- The Clinical Trials Department of the Egyptian Drug Authority (EDA) is responsible for evaluating, registering, and monitoring clinical trials in the country, and the drug importation department within EDA is responsible for providing approvals related to the importation of drugs, equipment, and other Clinical Trial Supplies. Notably, Egypt achieved a significant milestone in medicines regulation in December 2024, attaining maturity level 3 (ML3) in the WHO's global classification of national regulatory authorities. This achievement builds upon Egypt's earlier success in March 2022, when it reached ML3 for vaccine regulation (locally produced and imported). With this latest recognition, Egypt becomes the first country in Africa to achieve ML3 for both medicines and vaccines regulation, as assessed by WHO's Global Benchmarking Tool.

- The Supreme Council of Clinical Research Ethics (SCCRE) is the authority responsible for upholding the highest international standards in research ethics. Its responsibilities include reviewing clinical trial applications, maintaining the national clinical trial database, accrediting all IRBs/ethics committees, clinical trial sites, and CROs, as well as approving the exportation of biological samples to centralised laboratories outside of Egypt.

The aforementioned bodies work to ensure the safety and ethical standards of clinical trials conducted in the country and play a vital role in providing regulatory oversight and safeguarding the welfare of clinical trial participants with a mission to hit an overall Egypt regulatory startup timeline not exceeding 120 days through parallel submissions.

Egypt and KSA followed Jordan which was the first country to endorse a clinical trial law into action in 2001, based on the Declaration of Helsinki emphasising the importance of the formation of IRB and ICH–GCP (7).

The Jordanian Food and Drug Administration (JFDA) was established in 2003, and in 2004, it set up the Clinical Study Division to review applications for the site and IRB accreditation.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The approval process is sequential, requiring IRB approval followed by JFDA approval. Additionally, the JFDA issued guidance on the management of clinical trials during the COVID-19 pandemic.

Tunisia is another example from the MENA region where, in 2016, the Tunisian Ministry of Public Health took active steps to regulate the conduct of clinical trials in the country. Three Central Ethics Committees (CECs) were established to cover the North, South, and Central areas of Tunisia, with their locations linked to the National Coordinator Site. No local IRB reviews are required, which has significantly improved approval timelines.

Tunisia's MoH (8) submission is performed in parallel to CEC submission, however, approval can only be granted after CEC approval, The DPC (Data Privacy Committee; for external information) package should be submitted (radiology, laboratory, CRF) after CEC approval, and the acknowledgement of receipt should be submitted to the Direction de la Pharmacie et du Médicament (DPM). Tunisia was able to hit the shortest regulatory and startup timelines and was flagged as a quality destination.

In a significant step towards strengthening regional regulatory frameworks, the North African Medicine Regulatory Harmonisation (NA-MRH) Initiative was recently established. This initiative aims to unify regulatory efforts across Egypt, Libya, Tunisia, Algeria, Morocco, and Mauritania.

The first NA-MRH Steering Committee meeting was held in Cairo, Egypt, from 18 to 20 February 2025 where the Terms of Reference for the initiative were approved. The committee elected Egypt as Chair, Morocco as Co-chair, and Tunisia as the Secretariat. This development aligns with broader efforts to operationalise the African Medicines Agency (AMA) and to enhance regulatory harmonisation across the continent. The initiative has received strong support from AUDA-NEPAD's African Medicines Regulatory Harmonization (AMRH) Programme, the World Health Organization (WHO), and collaborating member states.

In conclusion, the number of clinical trials conducted in MENA has been on the rise, but MENA still lags behind other regions in terms of its global share of trials. However, with the witnessed regulatory evolution aiming at speedy startup and effective oversight of trials, more industry-sponsored trials will take place in MENA. Moreover, the development of national registries to capture data and insights from clinical trials will be crucial in building a comprehensive knowledge base to inform public health policies and guide the development of new treatments and therapies.

Abbreviations:
1) KSA: Kingdom of Saudi Arabia
2) UAE: United Arab Emirates
3) WHO: World Health Organization
4) CRO: Contract Research Organisation
5) GDP: Gross domestic product
6) IRB: Institutional Review Board
7) ICH-GCP: International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use - Good Clinical Practice
8) MOH: Ministry of Health

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

References:

- https://www.iqvia.com/-/media/library/white-papers/expected-growth-of-industry-sponsored-clinical-trials-in-the-middle-east-benchmarked-on-other-global.pdf?vs=1
- Unearthing The Potential Of The Clinical Trial Market In Middle East, Turkey And Africa (Meta) Region - IQVIA
- Worldbank
- ·https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group
- https://www.who.int/news/item/20-12-2024-egypt-s-regulatory-system-reaches-who-maturity-level-3-in-medicines-regulation
- Longtaal 2023 industry sponsored clinical trials, Clinical Trials Landscape Dashboard - Global

Authors:
Dr Sahar Ibrahim
Head of Clinical Operations, Middle East and North Africa, IQVIA

Dr Yasmin Nagaty, PharmD., BCPS
Regional Manager | The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP) CIO

Dr Sahar Ibrahim

Dr Yasmin Nagaty

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Celebrating Patient Engagement: The Made with Patients Awards 2025

Patient engagement is transforming healthcare, and the Made with Patients Awards celebrate the individuals and initiatives leading this change. Recognising contributions across medicines development, MedTech, digital health, and beyond, these awards spotlight those putting patients at the centre of healthcare innovation.

This year, the response has been exceptional, with over 223 nominations received - surpassing previous years. This surge reflects the growing momentum of patient engagement worldwide and the collective efforts of the community in sharing and promoting the Awards. A diverse multi-stakeholder jury of patient engagement experts has begun reviewing the submissions, marking the start of a thorough evaluation process.

The Awards welcomed nominations from a broad range of contributors, including patients, healthcare professionals, and industry leaders. Both emerging projects and well-established programmes will be considered, ensuring that impactful work at every stage is recognised. Categories include:

- **Best Tools Implementation** – Honouring creative adaptation of tools to enhance patient engagement.
- **Diversity, Equity & Inclusion (DEI)** – Recognising initiatives that ensure inclusivity and representation.
- **Systematic Meaningful Patient Engagement** – Celebrating organisations that embed patient engagement into their core mission.
- **Best Overall Initiative** – Highlighting models that integrate patient voices and demonstrate sustainable impact.
- **Rising Star** – For newcomers making significant strides in patient engagement.
- **Hall of Fame** – For seasoned champions with a proven track record of impactful patient engagement.

PFMD.org
Made WITH Patients

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The Awards ceremony will take place during the Patient Engagement Open Forum (PEOF), which will be held in person on 11 June 2025 in Italy. This special event will bring together a global community of changemakers dedicated to advancing patient engagement.

The ceremony will also be live-streamed, offering a unique opportunity to honour those making a meaningful impact while inspiring others to follow their example.

📢 Want to be part of this moment? Subscribe now to join the livestream and celebrate the excellence in patient engagement with us!

By celebrating these champions and initiatives, the Made with Patients Awards aim to inspire a shift towards a more inclusive and impactful health ecosystem worldwide. Each nomination represents a step towards building a future where patients are true partners in healthcare innovation.

Author:
Lidewij Vat, Senior Programme Director, PFMD, The Synergist

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

In this webinar, we will explore sex differences in cardiovascular pharmacology by examining specific examples of commonly used cardiovascular drugs. Following the presentation, an open discussion session will provide an opportunity to collectively draw conclusions and explore future directions in cardiovascular pharmacology. Participants are encouraged to contribute their expertise from other fields during the discussion session.

SPEAKER

Dr. Rubén Fuentes Artiles, M.D.
(University Clinic/Inselspital
Berne, Switzerland)

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

Register in advance for this webinar

After registering, you will receive a confirmation email containing information about joining the webinar.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Summary of the Webinar of 20 February 2025:

The 2024 Revision of the Declaration of Helsinki: A Step Toward More Global Research Ethics

Speaker: Professor Dr. iur Dominique Sprumont

Professor Dr. Dominique Sprumont is Professor of Health Law at the Law Faculty of the University of Neuchâtel (Switzerland). He is a WMA (1) academic partner and President of the Research Ethics Committee of Vaud, Switzerland (www.cer-vd-ch), and past vice-director of the Swiss School of Public Health.

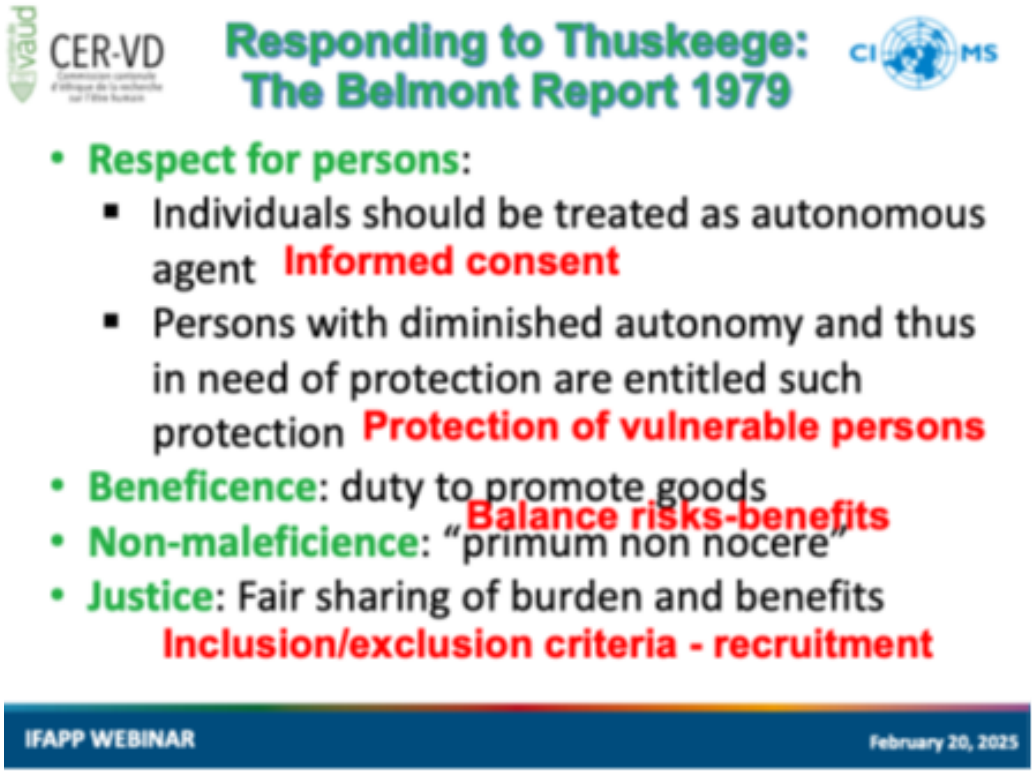
Overview

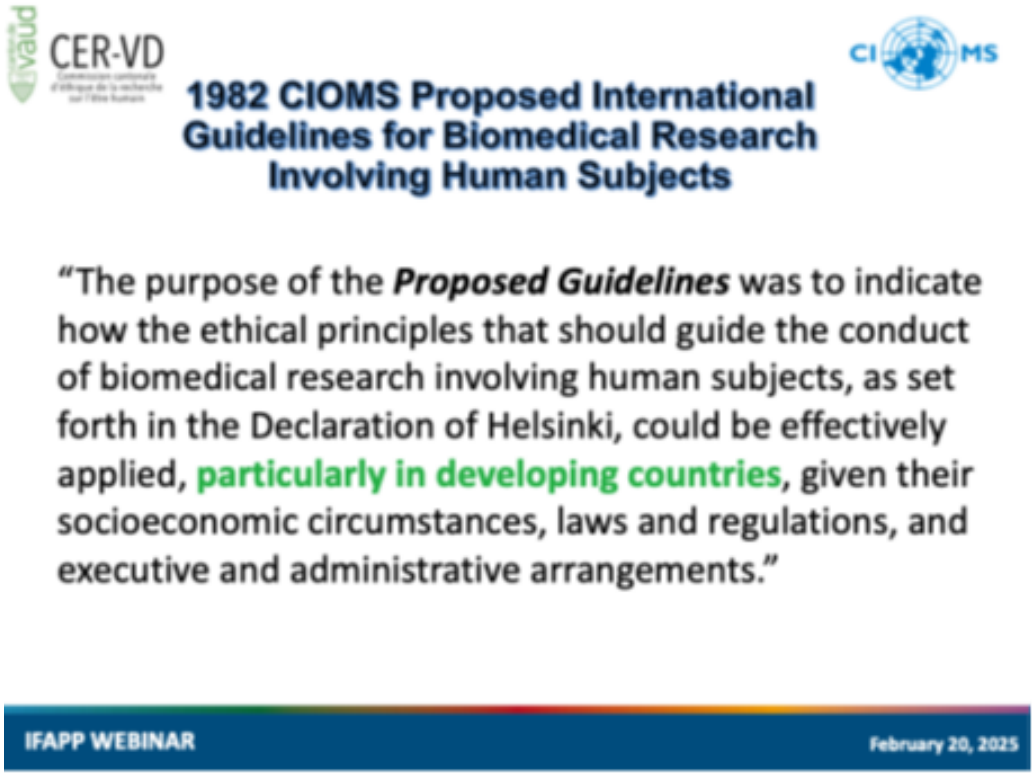
The Declaration of Helsinki (DoH; 2) is often recognised as the constitution of research ethics. Its latest revision encompasses all the fundamental principles that emerged recently in global ethics, starting with the 2016 CIOMS (3) International Ethical Guidelines. It strives towards reinforcing the respect for and protection of human research participants and the quality and social value of research. More than ever it demonstrates the engagement of the researchers towards the highest ethical and scientific standards in the respect of human rights.

Where we are coming from?

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

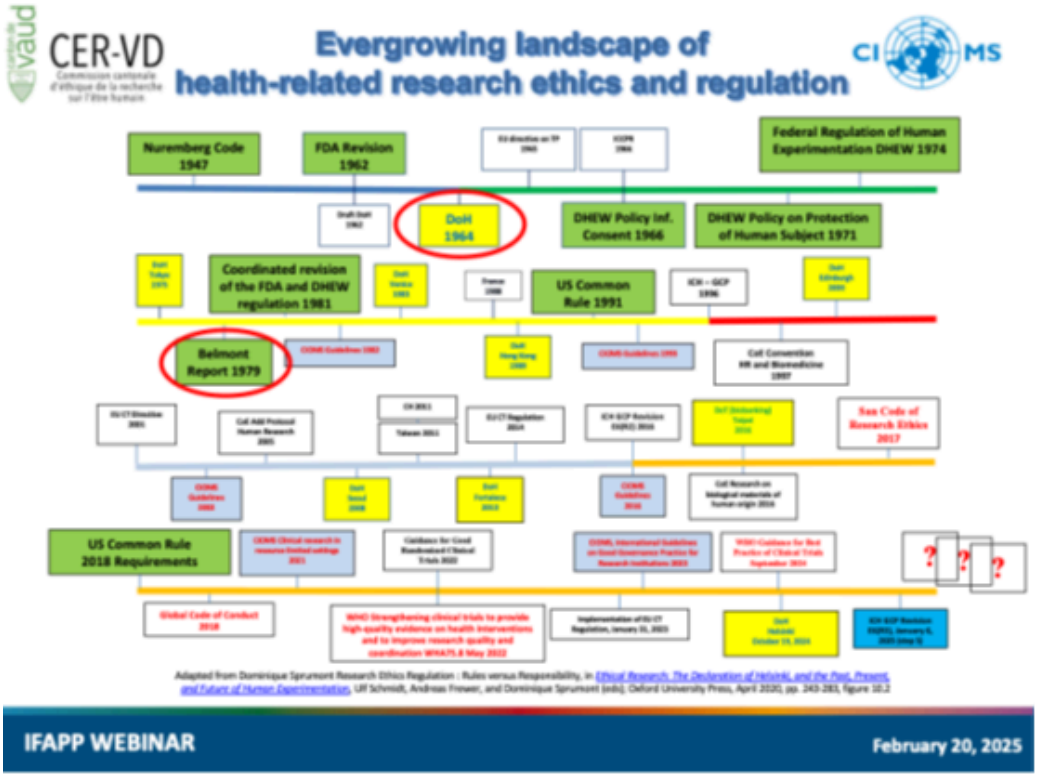
What were the first outcomes?





IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Where to find more and detailed information?



What are the fundamental changes?

The red numbers in the slides below reflect the amended articles

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

CONCLUSION

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

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

Abbreviations

1) WMA: World Medical Association
2) Declaration of Helsinki: https//www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
3) CIOMS: Council for International Organizations of Medical Sciences

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Don's Miss Out: ICPM 2025 is Fast Approaching!

Amsterdam, 9-11 April 2025

Our flagship event, the International Conference on Pharmaceutical Medicine (ICPM 2025), themed "Purpose for Future", is just around the corner! This is the perfect opportunity to connect with (international) colleagues, expand your network, and gain insights from esteemed speakers. Explore the inspiring programme on our website: www.icpm2025.com/programme.

A Special Milestone

ICPM 2025 also marks the 50th anniversary of IFAPP! Be part of this unique and historic moment in Pharmaceutical Medicine.

Programme & Registration

Please visit our website for the full programme and register now: https://icpm2025.com/registration/

We look forward to welcoming you to Amsterdam!

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: