



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

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

IFAPP
The only international
organisation for
everyone involved in
Pharmaceutical Medicine



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THIS ISSUE:

Page

- | | |
|--|-----------|
| 1. Boosting Pharmaceutical Education in Mexico: 2022 in a Nutshell | 1 |
| 2. It was Great Seeing Almost Full Meeting Rooms Again! | 3 |
| 3. A Look to the Italian Society of Pharmaceutical Medicine | 4 |
| 4. Easy Guide to Clinical Studies – A Practical Tool for Young Clinical Research Professionals | 6 |
| 5. Discussions for the Next Revision of the Declaration of Helsinki: Meetings of the WMA and IFAPP | 8 |
| 6. IFAPP Free Webinar: HTA Requirement in Relation to the EU Regulation - June 8th, 2023 | 13 |
| 7. Sponsorship of IFAPP Activities 2023-2024 | 15 |

Boosting Pharmaceutical Education in Mexico: 2022 in a Nutshell

As mentioned in previous issues, AMEIFAC has been promoting pharmaceutical education in Mexico for over 50 years, both among its members and in society in general, with the aim of providing updated information on new trends in the pharmaceutical industry from a scientific, regulatory, pharmacovigilance, market access, and other related disciplines perspective.

In line with the above, the AMEIFAC board carried out multiple activities throughout 2022 that allowed the association's influence to extend beyond the medical community, reaching other elements of the Mexican healthcare ecosystem, with the ultimate goal of expanding its impact to other Spanish-speaking countries in the Americas and facilitating international collaboration to share best practices.

During 2022, we had an ambitious plan that consisted of three educational pillars:

1. The realisation of monthly academic sessions that were broadcasted via Facebook live for all interested parties and are available for members in the multimedia library.

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The Global Newsletter on Pharmaceutical Medicine



2. The planning and execution of the national congress, which was held 100% virtually and featured the participation of 8 speakers of regional recognition.

3. The collaboration with other sister societies, such as the Mexican Association of Pharmacovigilance A.C. (AMFV), the National Association of Drug Manufacturers A.C. (ANAFAM), and the National System for Management of Medicine Packaging and Medical Waste A.C. (SINGREM).

The 2022 national congress of AMEIFAC took place from November 28th to 30th as a virtual event, which included three simultaneous pre-congress workshops that lasted 4 hours each and covered the following topics: Regulatory procedures before COFEPRIS, pharmacovigilance, and Data Generation and RWE. As for the main event, our agenda was composed of the following:

- Stand-alone lecture entitled: Medical excellence: A strategic commercial ally and liaison with physicians.
- Round table entitled: Role of MSL, DSL, and CSL in the day-to-day of the pharmaceutical industry.
- Round table entitled: Interaction with KOLs and the emergence of Digital Opinion Leaders (DOLs).
- Stand-alone lecture entitled: Experiences of the New Molecules Committee: From design to approval of innovators and biosimilars in Mexico.
- Round table entitled: Tendering and procurement of health supplies. Full review of the current process.
- Stand-alone lecture entitled: Management of medication packaging waste and its impact on counterfeit drugs.
- Stand-alone lecture entitled: Artificial intelligence in current medicine.
- Round table: Right to Health and access to medications.
- Stand alone: Neuro-Business.

Each of the presentations had the participation of great exponents in each branch of the transnational pharmaceutical industry, and in addition to all the above, we had the academic endorsement of the National Regulatory Committee of General Medicine.

Regarding our collaborations with other sister societies, AMEIFAC had the honour of participating in the national pharmacovigilance congress, where, through a stand, we were able to inform about academic activities and seek new affiliates. Additionally, our president, Dr. Manuel Lavariega, participated academically in an expert roundtable whose topic was patient-centred communication and initiatives to support patient awareness and the importance of pharmacovigilance.



In AMEIFAC, we have many more projects focused on the continuous training of our members, as well as initiatives that translate into a social impact that leads to contributing to a positive change in the health sector.

Dr. Alejandro Rangel-Delgado
General Secretary AMEIFAC



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The Global Newsletter on Pharmaceutical Medicine



It was Great Seeing Almost Full Meeting Rooms Again!

Since January the Czech Association of Pharmaceutical Medicine organised two major events: the “Course in Pharmaceutical Medicine” that took place in 6 days between January and March and “Meet the Expert” session “Hot Topics in Clinical Trials in 2023” on April 20, an event hosted and supported by the State Institute for Drug Control.

The second one dealt with three major topics: 1/ CTIS and its impact on clinical trials in Europe; 2/ Academic research and its support; and 3/ Environment for clinical trials in the Czech Republic. And what was discussed? CTIS has not yet delivered the promised simplification of the clinical trial approval process and improvement of the environment for clinical trials in the EU; however, most stakeholders believe in gradual improvement of the system. The State Institute for Drug Control and CZECRIN (Czech Clinical Research Infrastructure Network) provide significant support to non-commercial studies, but their number is still behind many developed countries. However, there are positive examples of technology transfers. The Czech Republic is generally perceived as a high-quality environment for clinical evaluations; nevertheless, there are significant areas for improvement (related to the digitisation of healthcare, the environment for decentralised studies or contractual relations with healthcare providers, and, therefore, the time required for start-ups in general).

Participants had the opportunity to discuss these topics with top experts from regulators, healthcare providers, pharmaceutical industry, contract research organisations and representatives of academic research. It was already the second meeting of this type and again brought an extremely high-quality discussion on hot topics of clinical trials.



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



The “Course in Pharmaceutical Medicine” organised by our Association together with the First Faculty of Medicine, Charles University Prague, was held already twelve times, this year for the first time with a module dedicated to Medical Devices. Other modules traditionally deal with Physiology and Pharmacology, Clinical Trials, Biostatistics and Pharmacoinformatics, Marketing Authorisation and Pharmacovigilance and Drug Pricing and Reimbursement. Since a couple of years ago we have allowed attending the whole course or individual module(s). We were happy to see around 30 graduates from the whole Course and tens of participants in individual modules (with the highest number in the Medical Device module which clearly shows the emerging importance of this area). It's very encouraging that in the era of virtual meetings and company e-learning there is still a substantial number of professionals interested in a broader picture of Pharmaceutical Medicine and in irreplaceable face-to-face discussions.

Authors:

Ondrej Slanar, Head of Institute of Pharmacology, First Faculty of Medicine, Charles University in Prague, President of the Czech Association of Pharmaceutical Medicine

Jiri Paseka, Member of Advisory Board, GCP-Service International, Board Member of the Czech Association of Pharmaceutical Medicine

A Look to the Italian Society of Pharmaceutical Medicine

The Italian Society of Pharmaceutical Medicine (SIMeF) is a non-profit organisation established in 2018, continuing the activities of the SSFA (Society of Applied Pharmacological Sciences founded in 1964). The organisation has since then aimed at promoting the study, research, and training of professionals in the field of pharmaceutical medicine and related disciplines. SIMeF represents Italy within IFAPP and FERQAS (Federation of European Quality Assurance Societies). This year, its nature as a non-profit organisation was officially recognised by the Italian Authorities. SIMeF counts about 1,000 members, belonging mainly to the pharmaceutical industry and contract research organisations, but also from Authorities and Ethics Committees. It is distinguished by the breadth of cultural interests, which extensively cover the whole area of applied pharmacology, drug, food supplements and medical devices, especially at the clinical level.

The governing body of SIMeF is the Executive Committee, elected every three years. Elections have just been held for the Executive Committee that will appoint the Society's institutional officers: the President, the Vice President, and the Secretary. SIMeF is a multidisciplinary society that operates through working groups (WG), under the guidance of working group coordinators, leading experts in the field of interest of the WG. Currently there are twelve WGs: Institutional Affairs; Legal Affairs; Medical Devices; Pharmacovigilance "E. Montagna"; Italian Group for Quality Assurance in Research (GIQAR); Italian Biostatistics Group (IBIG); Food Supplements; Market Access & HTA; Patient Partnerships; Clinical Research and Medical Affairs; Observational Studies – RWE; SIMeF Giovani (junior members). SIMeF Giovani is not a full-fledged WG, it is mainly aimed at bringing together young members under 35 and promoting their active collaboration with existing WGs.



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



SIMeF organises various activities aimed at promoting the study, research, and training of professionals in the field of pharmaceutical medicine. I will focus on three main areas:

- Scientific Conferences, Meetings, Training Courses:

SIMeF organises scientific conferences and meetings where professionals in the field of pharmaceutical medicine can share their research findings and exchange ideas. These conferences and meetings provide a platform for professionals to discuss emerging issues in the field and to identify areas for further research. SIMeF offers courses for professionals in the field of pharmaceutical medicine and participate in university masters and courses.

- Research and Publications:

SIMeF supports scientific research in pharmaceutical medicine and related disciplines; it also collaborates with other organisations and scientific societies, such as the Italian Society of Pharmacology, to conduct educational and research activities in the field. SIMeF official bulletin is "Il Giornale della SIMeF" (Journal of SIMeF). The online Journal of SIMeF, available on our website (www.simef.it in Italian), and on LinkedIn, publishes contributions by members on the activities of WGs and articles by external experts from academia, institutions, and companies. Articles, received after invitation by the Editorial Board or spontaneously submitted, can be written in Italian or English. The Journal also provides answers to technical/scientific questions submitted by readers and judged of general interest.

- Networking and Advocacy:

SIMeF provides a platform for professionals in the field of pharmaceutical medicine to network and collaborate. This networking helps to foster the exchange of ideas and to promote research collaborations. SIMeF advocates for the interests of professionals in the field of pharmaceutical medicine. The organisation works also with the regulators (Italian Medicines Agency, Ministry of Health) to promote policies that support the development and growth of the field.

In this brief and necessarily schematic article, I hope to have given an outline of SIMeF's activities; indeed, our Society is not only a point of reference for all professionals in Pharmaceutical Medicine and related disciplines but is also a meeting point for the different stakeholders in the field of pharmaceutical research and development and in healthcare in general.

Salvatore Bianco, MD

IFAPP Delegate of SIMeF



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The Global Newsletter on Pharmaceutical Medicine



Easy Guide to Clinical Studies – A Practical Tool for Young Clinical Research Professionals

Managing a clinical study is complex and time-consuming: there are regulatory requirements to fulfil, approvals to obtain, staff to train, and partnerships to build. In order to support research teams – and particularly young clinical research professionals – navigate the complex world of clinical research with ease, the experts of the Project Management Platform of the Swiss Clinical Trial Organisation (SCTO) have launched a beta version of their Easy Guide to Clinical Studies (Easy GCS).

The Easy GCS is structured in six study phases (from “basic” to “completion”) and eleven different subject areas (e.g., ethics and laws, study management, quality and risk, and safety). This guide enables clinical research professionals to quickly find answers to their questions. Indeed, the “basic” section provides visitors with background knowledge and definitions. Moreover, all information is presented with a simple and user-friendly layout by answering three pertinent questions: (1) What is it and why is it important? (2) What do I need to do? (3) Where can I get help? The answer to the last question provides clinical research professionals with references to relevant Swiss laws, to international guidelines (e.g., ICH GCP and ISO), links to useful tools, and information on how to access additional professional support within the SCTO Clinical Trial Units Network. The current beta version contains seven (out of eleven) complete subjects and subsequent subjects will follow shortly. Stay tuned!

Try out the Easy GCS now at: <https://www.easy-gcs.ch/entrypage.html>.

The Easy GCS tool is being developed by our experts in the SCTO’s Project Management Platform with support and expertise from our partners in the other SCTO Platforms, the Swiss Biobanking Platform (SBP), and the Swiss Group for Clinical Cancer Research (SAKK).

The SCTO Platforms were established in 2017 as a nationwide network of eight thematic and interconnected platforms in Switzerland. These platforms develop practical resources as well as innovative and freely available tools for clinical research professionals.

The SCTO Platforms are publicly funded by the Swiss State Secretariat for Education, Research and Innovation (SERI). To learn more about the SCTO Platforms and about specific tools visit our Tools & Resources website: <https://www.sctoplatforms.ch>. There you will also find tools specifically developed for young researchers such as the Clinical Research Careers website – centralising information and guiding young physicians throughout their research career.

Authors

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SCTO
PLATFORMS



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STUDY	Basic	Concept	Development	Set-Up	Conduct	Completion
Protocol						
Management						
Ethics and Laws						
Documents						
Safety						
Data Handling						
Statistics						
Quality and Risk	Risk Management Definitions Quality Management System (QMS) Risk-Based QMS Responsibilities	Study Feasibility	Study Risk Management Quality Assurance Quality Control Risk Communication		Risk Review Deviation Documentation Regulatory Inspections	Clinical Study Report Archiving
Monitoring						
Drug or Device						
Biobanking						

Figure 1. Easy GCS navigation grid ([https://www.sctoplatforms.ch/en/tools/easy-guide-to-clinical-studies-\(easy-gcs\)-186.html](https://www.sctoplatforms.ch/en/tools/easy-guide-to-clinical-studies-(easy-gcs)-186.html))

Figure 2. Facts and figures of the SCTO Platforms

SCTO Platforms: Facts and figures



The SCTO Platforms have existed since

2017



There are

8 SCTO Platforms



More than

90 people work in the platforms' teams



To date,

41 practical tools have been developed by the platforms

SCTO PLATFORMS



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The Global Newsletter on Pharmaceutical Medicine



Discussions for the Next Revision of the Declaration of Helsinki: Meetings of the WMA and IFAPP

Opening of the discussion for the next revision of the Declaration of Helsinki

The World Medical Association (WMA)'s Declaration of Helsinki (DoH) **[1]** provides a set of ethical principles of medical research involving humans, which is critically important for experts engaged in medicines development, as well as for patients and the public participating in research. The DoH is a set of requirements addressed by physicians to physicians. However, in order to facilitate collaboration with non-physician professionals and research participants, all these stakeholders need to have a sufficient common understanding of the updated, latest ethical principles. Such principles have been revisited according to the advancement of research methodologies as well as demands from the society. For this reason, the DoH has been amended several times as a “living document” **[2]**.

At the Council session in April 2022, the WMA decided to start the next revision process of the DoH, aiming at adopting the revised version at the General Assembly in Helsinki, Finland in October 2024. Its first version was adopted in Helsinki in 1964, thus the next year is the 60th anniversary and it will be the 10th amendment. The WMA considers the need to revise their documents every 10 years. 2023 is the tenth year since the latest revision of the DoH in 2013.

Some of the national member associations of the WMA were appointed by the Chair of Council to participate in a workgroup on the revision. Although some of the workgroup meetings are not open to public, the WMA provides opportunities of discussion in open forums. The first regional meeting for the revision of the DoH was held in Tel Aviv, Israel on December 9 to 11, 2022, followed by that in Sao Paulo, Brazil in February 24 and 25, 2023. The author participated in both of these two open conferences and will report some important points of discussions in these meetings. IFAPP's perspective and planning to facilitate discussions will be also introduced.

IFAPP's initiatives to facilitate discussions

IFAPP agreed in 2017 with the WMA on the Memorandum of Understanding (MoU) for mutual cooperation and is currently considering its renewal. Under the MoU, IFAPP formally submitted in 2019 its views on the issues to be considered for revision of the DoH (IFAPP TODAY 2022 No. 20 Jan) **[3]**.

In 2019, to promote data-driven research, members of the IFAPP Ethics Working Group (EWG) published a scientific paper **[4]** on the importance of linking the DoH and the Declaration of Taipei (DoT) on health databases and biobanks **[5]**. We also prepared an infographic describing the important points of the above paper (IFAPP TODAY 2021 No. 19 Nov/Dec) **[6]**. These issues related to data-driven research have been repeatedly discussed at the WMA regional meetings. The WMA and IFAPP have engaged to discuss the revision of the DoH with various stakeholders. IFAPP set up an online workshop at the ICPM in Athens in October 2022, inviting Dr. Jack Resneck Jr, workgroup chair of the revision of the DoH, the president of the American Medical Association (AMA), together with Dr. Otmar Kloiber, Secretary General of the WMA (IFAPP TODAY 2022 No. 29 Nov/Dec) **[7]**. The WMA and IFAPP are currently collaborating on another online workshop in June of this year.



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



Key points at the Regional Meeting in Tel Aviv: Consent for multiple data use and general issues

The first regional meeting for the revision of the DoH by the WMA focused on the ethical principles set out by the DoH in general and considered the issues that had been raised within and outside the WMA about the need for its revision. A particular focus of discussion was the nature of consent for the use of an individual's data on multiple occasions, for a variety of purposes. Unlike the traditional blanket consent, the idea of consent obtained by explaining the various possibilities for future research, including the governance framework of biobank and/or health database has been much discussed. Such type of consent is not only set out in the DoT, but also in the CIOMS guidelines [8]. However, during the discussion at the meeting it became clear that in some regions DoT had not been well acquainted. Much discussion was needed about how such type of broad consent could be authorized within personal data protection laws in each country. DoT, which is regarded as complementing the DoH, may be the ethical foundation for multiple use of individual data/samples, thus the DoT needs to achieve the same recognition and adherence as the DoH.

Other principles regarding the protection of vulnerable groups, as well as multi-stakeholder involvement were also shown to be an important point of discussion. It also seemed to be a unanimous agreement that the DoH would keep its nature of ethical principles and should avoid the style of detailed procedural regulations.

Key points at the Regional Meeting in Sao Paulo: Placebo debate

The regional meeting in Sao Paulo focused on placebo-controlled trials, which had raised many controversies since the 1990s. The ethical guardrails for placebo-controlled trials in the presence of best-proven intervention has led to major differences of opinions among the global research community.



From the left: Dr. Elliot Crigger, AMA Ethics Advisor; Dr. Urban Wiesing, WMA Ethics Advisor; Dr. Jung Yul Park, Professor at Korea University, now WMA Chair and at the time was also WMA Finance and Planning Committee Chair; Dr. Otmar Kloiber, WMA Secretary General.



From the left, Dr. Dominique Sprumont, University of Neuchatel, Switzerland; Executive Committee Member, CIOMS, Dr. Dirceu Greco, Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais, Dr. Miguel R Jorge, Former President, WMA; Brazilian Medical Association, Dr. Mariela Mautone, Professor at the University of the Republic (Udelar), Uruguay, Dr. Carla Saenz, Regional Ethics Advisor, Pan American Health Organization.



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



Dr. Jack Resneck Jr., President, American Medical Association; Workgroup chair of the revision of the DoH, WMA.

presentation by Professor Dirceu Greco, Professor Emeritus of Infectious Diseases and Bioethics at the Federal University of Minas Gerais, who explained that placebo-controlled trials were acceptable in Brazil only in the absence of best proven intervention, which was the position of the 2000 version of the DoH. He was one of the bioethicists who led the debate towards the 2000 revision. Subsequently, revising the 2002 Note of Clarification to 2008 version changed this justifiability condition to “no additional risk of serious or irreversible harm”. The 2016 CIOMS Ethical Guidelines risk threshold wording was set at a “minor increase above minimal risk”. There were also presentations from CONEP (National Commission for Research Ethics), which was a single national research review board to review specific types of clinical trials in Brazil, in addition to local research ethics committees. While global companies have been conducting a substantial number of clinical trials in Brazil, it has been noted that only one clinical trial has been rejected due to the principle of not permitting placebo-control when there is a best-proven intervention - the COVID-19 vaccine challenge trial.

Invited speakers included a staff from the US FDA. The US FDA had previously led the development of the ICH E10 guideline agreed in 2000 to discuss the choice of control group in clinical trials **[10]** The risk threshold of the placebo-control when there is a proven intervention is similar to the principles in the 2008 and 2013 versions of the DoH. However, 23 years later, the various guidelines (including those that are still in draft status, e.g., considerations on “external controlled trials”, **[11]**) introduced by FDA all seem to promote risk minimization in placebo-controlled trials. It appears that global companies in recent years have also changed their attitudes significantly from around 2000 and are continuing their efforts to minimize the risks of placebo-controlled trials. There were also presentations based on analyses of the scientific methodology of actual placebo-controlled trials from researchers engaged in these studies, as well as regional initiative such as Pan American Health Organization (PAHO), facilitating ethical and robust scientific research. Although the meeting did not provide explicitly certain direction of revision nor to make revision of the placebo clause, a major achievement was the formation of a forum for stakeholders with different views to exchange opinions in good faith.

Many IFAPP members are assumed to have been involved in discussion on the risks of placebo-controlled trials in the presence of best-proven intervention, e.g., in their professional job of designing clinical trial protocols or being involved in research ethics committee reviews, as well as obtaining informed consent from study participants, etc.

Certain Latin American regulators, most prominently in Brazil, have raised objections arguing that the global companies have conducted placebo-controlled trials in low-resource settings that cannot be conducted in developed countries, and some have explicitly rejected specific aspects of the DoH since its 2008 revision **[9]**. The AMA, leading the workgroup, has made clear its commitment to tackle, from the beginning, the most difficult dilemma for the international community to resolve, and to listen to the voices of Brazil and other Latin American countries.

The history of the debate over the placebo clause in the DoH and Brazilian authority's position was explained in a

DoH and Brazilian authority's position was explained in a

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In the future, we would like to facilitate further discussions on this issue involving collaborating members of IFAPP and colleagues outside of IFAPP, based on information of actual clinical trials as well as research review committees. The IFAPP Ethics Working Group welcomes those who are willing to join the discussion.

Series of planned webinars

IFAPP is planning to organise a series of webinars on the above-mentioned issues, as well as authoring papers or news articles in IFAPP TODAY. We hope that some of the experts with opinions on the directions of the revision of the DoH, as well as patients and the member of general public who understand the content of these discussions, can join as discussants of webinars or authors of papers. They should contact Chieko Kurihara (chieko.kurihara@nifty.ne.jp).

Chieko Kurihara, BSocSc. Specially appointed Professor, Kanagawa Dental University, and member of the IFAPP Ethics Working Group

References

- [1] World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. Adopted in June 1964, and last amended in October 2013. Available from: <http://www.wma.net/en/30publications/10policies/b3/index.html>
- [2] Parsa-Parsi R, Blackmer J, Ehni HJ, Janbu T, Kloiber O, Wiesing U. Reconsidering the Declaration of Helsinki. *Lancet*. 2013 Oct 12;382(9900):1246-7. Available from: [doi: 10.1016/S0140-6736\(13\)62094-2](https://doi.org/10.1016/S0140-6736(13)62094-2). PMID: 24120200.
- [3] Kurihara C. IFAPP Recommendations for the Revision of the Declaration of Helsinki, Version 2013. *IFAPP TODAY*. 2022; Jan (20): 3-7. Available from: <https://ifapp.org/static/uploads/2022/01/IFAPP-TODAY-20-2022.pdf>
- [4] Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Collia LF, Kleist P, Laranjeira LF, Matsuyama K, Naseem S, Schenk J, Silva H and Kerpel-Fronius S. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. *Front. Pharmacol*. 2020. 11: 579714. Available from: [doi: 10.3389/fphar.2020.579714](https://doi.org/10.3389/fphar.2020.579714)
- [5] The World Medical Association. The Declaration of Taipei on ethical considerations regarding Health Databases and Biobanks. 2002, last revised 2016. Available from: <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>
- [6] Kurihara C, et al. A proposal for the Revision of the Declaration of Helsinki to promote data-driven science and strengthening human subject protection. *IFAPP TODAY*. 2021; Nov/Dec (19): 13-5. Available from: <https://ifapp.org/static/uploads/2021/12/IFAPP-TODAY-19-2021.pdf>
- [7] Kurihara C, Crawley FP. Future revision of the Declaration of Helsinki: Dialogue with WMA in Athens. *IFAPP TODAY*. 2022; Nov/Dec (29): 5-8. Available from: <https://ifapp.org/static/uploads/2022/11/IFAPP-TODAY-29-2022.pdf>



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



[8] Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-related Research Involving Humans. 2016. Available from: <https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/>

[9] Homedes N, Ugalde A, editors. Clinical trials in Latin America: where ethics and business clash. Springer International Publishing Switzerland. 2014.

[10] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline: Choice of control group and related issues in clinical trials. Recommended for adoption at Step 4 of the ICH Process on 20 July 2000 by the ICH Steering Committee.

[11] United States Food and Drug Administration. Considerations for the design and conduct of externally controlled trials for drug and biological products. Draft, February 2023. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-and-conduct-externally-controlled-trials-drug-and-biological-products>



June 8th, 2023
2:00 pm - 3:00 pm CET

HTA REQUIREMENTS IN RELATION TO THE EU REGULATION

A German perspective



eunethta



HTA requirements in relation to the EU Regulation

Speaker

Dr. Stephanie Said

Scientific Advisor, Senior Project Manager

Head of EUnetHTA 21 JSC Secretariat

The Federal Joint Committee
Gemeinsamer Bundesausschuss (G-BA)

TOPIC:

The REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance) sets out the frame for cooperation of national Health Technology Assessments.

How does it work? Which kind of impact has the new regulation on the national decision making? Which steps are taken to reach the goal of a harmonised approach to a European Assessment?

Dr. Said will give an in-depth information about the involvement of Germany in the development of the process, the steps already taken e.g., by EUnetHTA 21 and the perspectives of the implementation of the regulation.

G-BA

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

The G-BA must put every new active pharmaceutical ingredient through an early benefit assessment within six months after it is launched on the German market. During the early benefit assessment, the G-BA examines whether the drug is really something new: if it offers patients greater benefit than comparable treatments that are already available.

REGISTRATION

- This webinar is free to everybody
- Click [here](#) for registration

Time Schedule

08:00 - 09:00 AM EST

01:00 - 02:00 PM GMT

02:00 - 03:00 PM CET

09:00 - 10:00 PM JST



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine



Sponsorship of IFAPP Activities 2023-2024

2023 is a milestone year for IFAPP in relation to its history. We are celebrating the 50th anniversary of IFAPP since its inauguration in April 1973, and we are pleased to share our Pharmaceutical Medicine activities and sponsorship opportunities with interested parties.

Organisations who share our vision of scientific and educational programmes which advance Pharmaceutical Medicine to meet the needs of patients are invited to support us by applying for sponsorship of our activities for 2023-2024.

As a not-for-profit organisation IFAPP appreciates the support it may receive from institutions or organisations with a passion for enhancing the knowledge, expertise, and skills of Pharmaceutical Medicine worldwide.

International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

IFAPP is a worldwide network of National Member Associations and Individual Affiliates in 32 countries

2023/04/30



More than 6,000 members around the globe are visiting our website, follow our activities and receive our monthly Newsletter

IFAPP Sponsorship Proposals 2023

1

We are happy to see a growing reader community of our IFAPP TODAY monthly Newsletter that stay up to date with our specialty.



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Advertising Options

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and sent to IFAPP
Members

• Advertisement Sizes and Rates

Format	Width	Height	Rate
Ad 1/1 page	188 mm	255 mm	1000 EUR
Ad 1/2 page horizontal	188 mm	90 mm	600 EUR
Ad 1/2 page upright	91 mm	200 mm	600 EUR
Ad 1/4 page	91 mm	100 mm	400 EUR

Our National Member Associations and Individual Affiliates contribute their financial assistance, and we are excited to notice the continuous participation of increasing Pharmaceutical Medicine professionals joining the IFAPP 2023 online educational programme as well as the recent ICPM 2022 and IFAPP Working Groups scientific publications and activities.

Our IFAPP 2023-2024 strategy is including innovative initiatives such as the 'Next Generation Pharmaceutical Medicine Leaders' programme with tailored development recognitions and events targeting future discipline and career perspectives for young, middle, and senior Pharmaceutical Medicine colleagues.

In the pursue of our vision and mission and for fulfilling the commitment to our members we would need valuable sponsors to support our continuing education programme in Pharmaceutical Medicine and accompanying activities.

Educational and or research publication grants would be also communicated, for scientific projects.

The details of the potential sponsor contributions are described in the tables here below.



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SPONSORSHIP CATEGORIES

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3. **Silver Sponsor** (6,000€ + X%VAT)
4. **Supporter** (3,000€ + X%VAT)
5. **Other** (1,500€ + X% VAT)

GRANTS

1. **Educational activities – e.g., Summer School, Workshops, Podcasts**
2. **Research activities, Publication support**
3. **Other**

IFAPP Sponsorships proposals 2023

2

VAT % will depend on sponsor's country tax requirements. Please contact the IFAPP Secretariat for detailed information.

The benefits for our sponsors are presented as illustrated in the following tables.



Platinum Sponsor

- Thanking letter to the sponsor
- Reference of the sponsor's logo and name in the annual list of sponsors, on the IFAPP website, platinum group.
- Advertisement of the sponsor in IFAPP TODAY, a full-page advertisement in each of 10 annual issues and in a series of 3 webinars.

Gold Sponsor

- Thanking letter to the sponsor
- Reference of the sponsor's logo and name in the annual list of sponsors, on the IFAPP website, gold group
- Advertisement of the sponsor in IFAPP TODAY, a full-page advertisement in 8 annual issues or half-page advertisements in 10 annual issues and in a series of 2 webinars

Silver Sponsor

- Thanking letter to the sponsor
- Reference of the sponsor's logo and name in the annual list of sponsors, on the IFAPP website, silver group
- Advertisement of the sponsor in IFAPP TODAY, a full-page advertisement in 6 issues and in 1 webinar



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IFAPP Sponsorships

Supporter

- Thanking letter to the sponsor
- Reference of the sponsor's logo and name in the annual list of sponsors, on IFAPP website, supporter group
- Advertisement of the sponsor in IFAPP TODAY, a full-page advertisement in 3 annual issues or half-page advertisements in 6 issues

Other

- Thanking letter to the sponsor
- Reference of the sponsor's logo and name in the annual list of sponsors, on IFAPP website, "other" group
- Advertisement of the sponsor in IFAPP TODAY, a quarter-page advertisement in 3 issues

Digital Advertisement Requirements:

The ad must be fair, balanced, and corporate in content, following international standards and stored as a print-optimised PDF file and containing all elements necessary for the correct output. Please send it prior to the closing date via e-mail to the IFAPP Secretariat (secretariat@ifapp.org).

Publication & Closing Dates:

Please contact the IFAPP Secretariat for the publication & closing dates for your advertisement(s). Detailed information on sponsorship opportunities will be available soon at www.ifapp.org, section "sponsors" on the menu.

IFAPP will gratefully acknowledge sponsorships and financial support from the sponsoring companies.

We would very much appreciate you to consider our proposal of sponsorship opportunities. Please feel free to contact us if you need more information or a differentiated approach.

Sincerely yours

IFAPP Secretariat

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THE FLAG

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IFAPP Communication Working Group

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

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