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.
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.
- Stand-alone lecture entitled: Experiences of the New Molecules Committee: From design to approval of innovators and biosimilar drugs 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
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.
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-learnings 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 (SIeMeF) 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. SIeMeF 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. SIeMeF 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 SIeMeF 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. SIeMeF 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; SIeMeF Giovani (junior members). SIeMeF 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.
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
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
Melanie Glaettli, PhD, Swiss Clinical Trial Organisation (SCTO)
Synøve Otterbech, PhD, Cantonal Hospital St. Gallen (KSSG)
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
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.
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.
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.
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**


HTA Requirements in Relation to the EU Regulation

A German perspective

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

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

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

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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

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

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